Nos. 22-1819(L), 22-1822

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CITY OF HUNTINGTON, WEST VIRGINIA and
CABELL COUNTY COMMISSION,
Plaintiffs-Appellants,
v.
AMERISOURCEBERGEN DRUG CORPORATION, et al,
Defendants-Appellees.

On Appeal from the United States District Court for the
Southern District of West Virginia, Huntington Division
Case Nos. 3:17-cv-01362 and 3:17-cv-01665, (Hon. David A. Faber)

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 22-1819 Caption: City of Huntington, et al v. AmerisourceBergen Drug Corporation, et al

Pursuant to FRAP 26.1 and Local Rule 26.1,

AmerisourceBergen Drug Corporation
(name of party/amicus)

who is Appellee, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☑ YES ☐ NO
If yes, identify all parent corporations, including all generations of parent corporations:

AmerisourceBergen Drug Corporation is a subsidiary of AmerisourceBergen Corporation and AmerisourceBergen Services Corporation.

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Kim M. Watterson Date: March 24, 2023

Counsel for: AmerisourceBergen Drug Corporation

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

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No. 22-1819 Caption: City of Huntington, et al v. AmerisourceBergen Drug Corporation, et al

Pursuant to FRAP 26.1 and Local Rule 26.1,

Cardinal Health, Incorporated
(name of party/amicus)

who is Appellee, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☑ YES ☐ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
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Signature: s/ Enu Mainigi Date: March 24, 2023

Counsel for: Cardinal Health, Incorporated

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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No. 22-1819 Caption: City of Huntington, et al v. AmerisourceBergen Drug Corporation, et al

Pursuant to FRAP 26.1 and Local Rule 26.1,

McKesson Corporation
(name of party/amicus)

who is Appellee, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☑ YES ☐ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
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Signature: s/ Paul W. Schmidt Date: March 24 , 2023

Counsel for: McKesson Corporation

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INTRODUCTION

Plaintiffs the Cabell County Commission and City of Huntington, West Virginia (collectively, "Plaintiffs" or "Cabell/Huntington") sued three wholesale distributors—AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, Inc. and McKesson Corporation (collectively, "Distributors")—for allegedly causing the opioid epidemic in Plaintiffs' community.

Distributors did not dispute the existence of an opioid epidemic in Cabell/Huntington. Instead, the central trial issues were whether Distributors caused that epidemic and whether their conduct in shipping the volume of prescription opioids needed to fill legitimate prescriptions was wrongful.

Over the course of a ten-week trial, the Honorable David A. Faber heard exhaustive testimony on these issues from 70 witnesses, and admitted hundreds of documents into evidence. Following trial, the court made detailed factual findings—many based on testimony from Plaintiffs' own witnesses—that Distributors did not cause the opioid epidemic in Cabell/Huntington and that they did not act unreasonably in supplying prescription opioids in response to legitimate prescribing.

Specifically, and drawing largely on undisputed testimony, the court found that Distributors—who perform the core function of ensuring that pharmacies and patients have access to medicines—shipped opioids to Cabell/Huntington pharmacies because doctors wrote legitimate prescriptions based on then-prevailing

standards of care. The volume of prescription opioids in Cabell/Huntington increased because the medical standard of care for treating pain changed. In response, doctors significantly expanded their opioid prescribing for a broader range of conditions—including, most notably, for chronic non-cancer pain. This led to unused medicines that were "diverted" after being dispensed to patients—the medicines were shared, stolen, or sold on the illegal market, creating unintended harms of abuse and addiction.

Although the overwhelming majority of doctors were acting in good faith, the expanded supply of prescription opioids caused by doctors' increased prescribing became the foundation for the opioid epidemic. Distributors did not cause changes in the standard of care or the resulting increased volume of prescription opioids, and the evidence established that Distributors substantially complied with their regulatory obligations and acted reasonably in shipping medicines prescribed by doctors to treat their patients.

On appeal, Plaintiffs do not establish, or even meaningfully argue, that the court's fact-findings were clearly erroneous—nor could they, given the overwhelming record support for these findings. Plaintiffs also do not establish legal error in the court's carefully reasoned decision, and their legal arguments provide no basis to set aside the unchallenged factual findings that are alone dispositive of this appeal.

STATEMENT OF THE ISSUES

1. Whether the court's findings of fact that Plaintiffs failed to prove causation were clearly erroneous where the evidence established that Distributors did not cause either an "oversupply" or diversion of prescription opioids.

2. Whether the court's findings of fact that Plaintiffs failed to prove proximate causation were clearly erroneous where the evidence established that Distributors' conduct in shipping prescription opioids to licensed pharmacies was too remote from Plaintiffs' alleged harms.

3. Whether the court's findings of fact that Plaintiffs failed to prove "unreasonable" conduct by Distributors were clearly erroneous where the evidence established that Distributors acted reasonably in shipping prescription opioids needed to fill legitimate prescriptions, and that Distributors substantially complied with their obligations under the Controlled Substances Act ("CSA").

4. Whether the court correctly held that West Virginia public nuisance law does not extend to the distribution and sale of lawful products, where no decisions of the Supreme Court of Appeals of West Virginia have applied public nuisance law outside the context of interference with public resources or property.

5. Whether the court correctly found that Plaintiffs' requested relief was not a proper abatement remedy for a public nuisance, where Plaintiffs were not seeking to address Distributors' alleged nuisance-creating conduct but instead were

seeking monetary relief for programs and services to treat personal injuries and associated harms of opioid abuse and addiction.

STATEMENT OF THE CASE

Distributors are "wholesale distributors of pharmaceutical and other products." Joint Appendix ("JA") 6342. Distributors fill the "important" logistical role of providing pharmacies and hospitals with medicines and other medical supplies. JA6342.

Plaintiffs sued Distributors along with 40 manufacturers, 19 pharmacies, five prescription benefit managers, and eight members of the Sackler family, alleging all were responsible for causing the opioid epidemic in their community. JA6341n.1. To secure early remand from the multidistrict proceeding pending in the Northern District of Ohio (*In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804) for purposes of conducting a "bellwether" trial, Plaintiffs severed all defendants except Distributors, waived a jury trial, and disclaimed compensatory damages.

Plaintiffs proceeded to trial against Distributors on a single cause of action for public nuisance. They sought approximately $2.5 billion in monetary relief for what they termed "abatement" of the alleged nuisance.

One year after trial, the court issued a 184-page opinion entering judgment in favor of Distributors based on multiple independent factual and legal grounds,

supported by more than 125 pages of fact-findings and more than 775 record citations.

The court found that "there is an opioid epidemic in the United States," JA6340, and that Cabell/Huntington "are among the West Virginia communities hardest hit by the opioid epidemic," JA6356. Distributors did not contest these points at trial, but instead argued that they did not engage in wrongful conduct and did not cause the opioid epidemic or its resulting harms, as a matter of fact and law. The court agreed.

The court based its judgment on five separate conclusions of fact and law. Each conclusion provides an independently sufficient basis for the court's judgment. Plaintiffs therefore cannot prevail on appeal unless the Court reverses all five conclusions.

I. The Court Found That Plaintiffs Failed To Prove Causation.

A. The Court Found That Distributors Did Not Determine the Volume of Prescription Opioids.

Plaintiffs' liability theory was that Distributors shipped an "unreasonable" or "excessive" volume of prescription opioids into Cabell/Huntington. JA95, JA145. But the court found as a matter of fact that "[d]octors in Cabell/Huntington determined the volume of prescription opioids that pharmacies in the community ordered from [Distributors] and then dispensed pursuant to those prescriptions." JA6468. Distributors "shipped prescription opioids only to licensed pharmacies in

response to demand created by prescriptions." JA6499-6500. Thus, the court concluded, "the volume of prescription opioids was determined by doctors, not distributors." JA6470.

The court also found that "[t]he opioid crisis would not have occurred if prescribing opioids had not become standard practice in managing acute and chronic pain." JA6462. This "standard practice" emerged because, "[b]eginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids." JA6438. The changes in the standard of care sprang from the "notion that the medical community was not doing enough to treat pain," which "persisted into the 2000s." JA6435. Thus, doctors—who "prescribe medications based on the then-prevailing standard of care," JA6435—"began to prescribe opioids for a broader range of conditions, most notably, for the long-term treatment of chronic pain." JA6458-6459. "[B]y the mid-2000s," as Plaintiffs conceded, "the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions." JA6459 (quoting Plaintiffs' Complaint). The court catalogued the evidence establishing this change in the standard of care over nearly 50 pages of its decision, supported by more than 200 citations to the trial record. JA6432-6479. Importantly, "there was no evidence presented for the trier of fact to find that [Distributors] had anything to do with changing the standard of care." JA6463.

Consistent with the testimony of Plaintiffs' witnesses, the court found that the "high volume of opioid prescriptions" resulting from the changed standard of care "became the foundation for the overall expansion [of] . . . opioid-related harms." JA6469 (quoting Plaintiffs' expert epidemiologist). This point was uncontested. For example, the West Virginia Board of Medicine concluded "that the opioid epidemic was fueled primarily by doctors liberally prescribing opioids," JA6475, and West Virginia's Opioid Response Plan likewise concluded "that 'a critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain,'" JA6461.

Testifying on behalf of Plaintiffs, a former senior West Virginia public health official—currently serving as Director of the Office of National Drug Control Policy—described a medical "'culture' of writing 'several more days of prescriptions' than required to treat the given condition." JA6459. He testified that "[i]t's probable for a good doctor to make a good sound judgment for the need of opioids, but make a mistake on the duration of the need of opioids. So, instead of three days, you write for 30 days, that's a problem." JA6459-6460. Plaintiffs' expert epidemiologist confirmed this point, testifying to a "common pattern whereby people have unused medication from an opioid prescription," JA2461:22-23, including estimates "that 90 percent of patients prescribed opioids after surgery have

unused medication, most of which is not disposed or stored safely," JA2472:21-2473:3.

This good-faith medical decision-making, involving what Plaintiffs' witnesses described as "excessive prescriptions" and "overprescribing by doctors," JA6515, resulted in diversion after pharmacies dispensed the medicines—namely, "unused prescription opioids diverted for [m]on[e]tary value, [or] bartered for no cost among family and individuals in a shared social network," JA6460 (quoting Plaintiffs' expert epidemiologist).[1] Plaintiffs' witnesses consistently described this pattern of "medicine cabinet diversion" arising from the sharing, sale, or theft of unused prescription opioids after pharmacies dispensed them to patients.[2]

[1] The term "diversion" refers to the transfer of controlled substances to illicit channels, which includes persons for whom they were not prescribed. JA2366:24-2367:1. "Diversion" of prescription opioids can occur when they are in (1) Distributors' custody, (2) pharmacies' custody, or (3) patients' custody after being dispensed by pharmacies. There was no evidence of diversion of opioids in Distributors' or their pharmacy customers' custody. JA6507, JA6508.

[2] *See* JA2062:2-7 ("[I]f you prescribe for a tooth pull 30 days worth of opioids at a dentist, then those—29 days of that opioid is going to sit in your closet. And your kids are going to get their hands on it or somebody else is going to get their hands on it."); JA2461:4-24 (it is "a common pattern whereby people have unused medication from an opioid prescription" that is subsequently diverted); JA2311:8-18 (three out of four people who misuse prescription opioids use drugs prescribed to someone else); JA2521:13-2522:7 (legitimately obtained pills were often subsequently diverted by being "traded," "sold" or stolen through "break-ins from people seeking drugs from medicine cabinets"). *See also* Br. 7 (diversion includes "consumers selling or giving away their medications," "acquaintances stealing drugs (so-called 'medicine cabinet' diversion)," and "illegal trafficking").

B. The Court Found That Distributors Did Not Cause Diversion.

The court found that "Plaintiffs offered no evidence of any diversion [of prescription opioids] from [Distributors'] pharmacy customers in Cabell/Huntington," JA6429, and that the "lack of evidence of pharmacy-level diversion on the part of [Distributors'] pharmacy customers is fatal to [P]laintiffs' claims," JA6508. The court additionally rejected "Plaintiffs' claim that [Distributors'] purported violations of the CSA and its implementing regulations caused an opioid epidemic . . . because there is no evidence that any such violation caused opioid diversion, properly understood." JA6500.

The evidence instead established that "unused prescription opioid[s]" were diverted ***after*** being dispensed by pharmacies, JA6460, and involved "criminal actions of third parties over whom [Distributors] had no control, including the persons to whom the medicines were prescribed and those involved in diverting the prescription opioids," JA6430-6431. Thus, the court found "there is no admissible evidence . . . that [Distributors] ***caused the diversion*** that resulted in an opioid epidemic." JA6511.[3]

II. The Court Found That Plaintiffs Failed To Prove Proximate Causation.

Separate from its threshold causation findings that Distributors did not cause either an "oversupply" or diversion of prescription opioids, the court also found that

[3] All emphases are added unless otherwise indicated.

the alleged harms (primarily, increased drug addiction and abuse) were too remote from Distributors' conduct to establish ***proximate*** causation. JA6511-6515. The court found that prescribing by doctors, dispensing by pharmacists, sharing by patients, and thefts and sales by criminal actors involved in "diversion of the drugs to illegal usage" ***all*** stood between Distributors' conduct in shipping prescription opioids to their pharmacy customers and Plaintiffs' alleged harms. JA6515; *see also* JA6430-6431.

Thus, as a matter of fact, the court concluded that Plaintiffs "failed to meet their burden to prove that [Distributors'] conduct was the proximate cause of their injuries." JA6515.

III. The Court Found That Plaintiffs Failed To Prove Unreasonable Conduct by Distributors.

The court also found that Plaintiffs failed to prove their public nuisance claim because they did not establish an "unreasonable interference with a right common to the general public." JA6496.

The court found that "[t]he overwhelming majority of doctors were acting in good faith when they made the decision to prescribe opioids," JA6472, and that "the distribution of medicine to support the legitimate medical needs of patients as determined by doctors exercising their medical judgment in good faith cannot be deemed . . . unreasonable," JA6498. The court found "***no evidence*** that ties any of [Distributors'] shipments to a pill mill in Cabell/Huntington," JA6479, and "***no***

evidence that [Distributors] ever distributed controlled substances to any entity that did not hold a proper registration from DEA or license from the West Virginia Board of Pharmacy," JA6480.

The court also found that "[a]t all relevant times, [Distributors] had in place suspicious order monitoring . . . systems as required by the CSA and its implementing regulations," JA6369; Distributors engaged in extensive due diligence of their customers and their customers' orders and identified and reported suspicious orders to DEA, JA6369-6403; and DEA was aware of and approved Distributors' compliance programs, JA6375, JA6383, JA6391. Based on these findings, the court devoted a 34-page section of its findings to the conclusion that Distributors "Substantially Complied with Their Duties" to "Design and Operate" a suspicious order monitoring system and to "Report Suspicious Orders." JA6369-6403.

The court separately found that "[P]laintiffs failed to show that any alleged violations based upon a failure to report suspicious orders by [Distributors] contributed to the volume of opioids distributed in Cabell/Huntington." JA6431n.5.

IV. The Court Held That West Virginia Public Nuisance Law Does Not Apply to the Distribution and Sale of Lawful Products.

The court's conclusions on causation and "reasonableness"—each independently dispositive of Plaintiffs' claim—assume that West Virginia public nuisance law applies to the distribution of lawful products. But the court made a

separate and independent legal holding that West Virginia public nuisance law does not extend "to the sale, distribution and manufacture of opioids." JA6496.

In reaching this conclusion, the court surveyed more than a century of West Virginia public nuisance decisions, concluding that they uniformly involved interferences "with public property or resources," JA6490, and that the Supreme Court of Appeals of West Virginia has never "held that distribution or sale of a product could constitute a public nuisance," JA6491.

V. The Court Held That Plaintiffs' Requested Relief Was Not a Proper Abatement Remedy.

Finally, the court held that Plaintiffs' requested relief—a monetary award for treatment of personal injuries and other harms associated with opioid abuse and addiction—was not a proper equitable remedy. JA6485-6486, JA6515-6520. The court found that Plaintiffs were "not seeking to 'abate' (enjoin or stop) the nuisance," JA6518, and that their requested remedy instead was directed, "virtually in its entirety, . . . at treating or otherwise addressing drug use and addiction, not at any of [Distributors'] alleged nuisance-causing conduct," JA6518-6519; *see also* JA6485.

For these reasons, "and upon a full trial record," the court held that "under the facts of this case, the relief that [P]laintiffs seek is not properly understood as abatement." JA6520.

STANDARD OF REVIEW

The trial court's "factual findings may be reversed only if clearly erroneous, while conclusions of law are examined de novo." *Nat'l Fed'n of the Blind v. Lamone*, 813 F.3d 494, 502 (4th Cir. 2016). "Under the clearly erroneous standard, a trial court's determination should be affirmed unless the Court is 'left with the definite and firm conviction that a mistake has been committed.'" *Andrews v. Am.'s Living Ctrs., LLC*, 827 F.3d 306, 312 (4th Cir. 2016) (quoting *Mallory v. Booth Refrig. Supply Co.*, 882 F.2d 908, 909 (4th Cir. 1989)); *see also Equinor USA Onshore Prop. Inc. v. Pine Res., LLC*, 917 F.3d 807, 813 (4th Cir. 2019). Further, a trial court's credibility determinations are entitled to "the highest degree of appellate deference." *Evergreen Int'l, S.A. v. Norfolk Dredging Co.*, 531 F.3d 302, 308 (4th Cir. 2008).

REGULATORY BACKGROUND

The court devoted extensive attention to the legal framework governing the distribution of controlled substances and to fact-findings addressing Distributors' compliance with their regulatory and statutory obligations.

DEA is charged under the CSA with determining whether it is in the public interest to register distributors of controlled substances. 21 U.S.C. §823(b). In making that determination, DEA is required to consider a non-exhaustive list of factors, including the distributor's "maintenance of effective controls against

diversion" of controlled substances "into other than legitimate medical, scientific, and industrial channels." *Id*. Applying this public interest standard, DEA repeatedly re-registered Distributors and their distribution centers throughout the relevant time period.[4]

The CSA's implementing regulations specify that DEA "shall use the [regulations'] security requirements" to determine whether a registrant (*e.g.*, a wholesale distributor) maintains "effective controls against diversion." 21 C.F.R. § 1301.71(a). While those security requirements "largely address the physical handling and security of controlled substances," JA6363, which were not at issue at trial, one provides that registrants shall "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and "inform [DEA] of suspicious orders when discovered," 21 C.F.R. § 1301.74(b).[5]

The regulation defines a "suspicious order" as including orders of "unusual size," "unusual frequency," or "deviating substantially from a normal pattern." *Id*. As witnesses repeatedly acknowledged, this open-ended definition can include orders that are "unusual" or "deviate" from normal patterns for legitimate reasons,

[4] *See* JA2127:20-2128:5; JA2194:20-2195:9; JA2234:1-19.

[5] Generally and in this litigation, these are called suspicious order monitoring ("SOM") systems. The orders at issue in this litigation are those placed by Distributors' pharmacy customers.

and orders that are unlikely to be diverted.[6] Beyond this generalized definition, "DEA does not and will not tell a distributor whether an order is suspicious but, rather, leaves that decision to the distributor." JA6364 (citing Plaintiffs' DEA witnesses).

The CSA "regulations do not require strict compliance." JA6363 (quoting *In re Nat'l Prescription Opiate Litig.*, 2021 WL 3917174, at *3 (N.D. Ohio Sept. 1, 2021)). Rather, "[s]ubstantial compliance with the relevant security requirements may be deemed sufficient by the DEA." JA6363; 21 C.F.R. § 1301.71(b).

SUMMARY OF ARGUMENT

The court entered judgment for Distributors based on five separate conclusions, each of which independently supports the judgment. Plaintiffs do not establish (or even meaningfully argue) that the findings of fact underlying those separate conclusions are clearly erroneous—nor could they. The court's analysis of the legal issues was also demonstrably correct. For these reasons, this Court should affirm the judgment.

1. ***Plaintiffs Failed to Prove Causation***. In response to Plaintiffs' core allegation that Distributors shipped an "unreasonable volume" of prescription opioids that "caused an opioid epidemic," JA6500, the court found as a matter of fact that Plaintiffs "failed to meet their burden of proving causation." JA6511. This

[6] *See* JA1361; JA1393, JA1394; *see also*, *e.g.*, JA1241, JA1242.

was based on the court's fact-findings that (1) "the volume of prescription opioids was determined by doctors, not distributors," JA6470, and (2) "there is no admissible evidence in this case that [Distributors] caused the diversion that resulted in an opioid epidemic," JA6511. The court found that "***[n]o culpable acts by [Distributors]*** caused an oversupply of opioids in Cabell/Huntington." JA6499.

The determination of causation is a question of fact, *Hatten v. Mason Realty Co.*, 135 S.E.2d 236, 238 (W.Va. 1964), and Plaintiffs do not even address the court's fact-findings of no causation—let alone show they are clearly erroneous. That alone defeats their public nuisance claim.

2. ***Plaintiffs Failed To Prove Proximate Causation***. The court found that Distributors' conduct in shipping prescription opioids to their licensed pharmacy customers was too remote from Plaintiffs' alleged injuries, which occurred only ***after*** doctors prescribed the medicines and pharmacies dispensed them—both in the exercise of independent professional judgment—and patients or third parties then illegally diverted them to illicit use.

Because "[a] remote cause of injury is insufficient to support a finding of proximate cause," JA6512, the court found as a matter of fact that Plaintiffs "failed to meet their burden to prove that [Distributors'] conduct was the proximate cause of their injuries," JA6515. Plaintiffs' brief does not address this remoteness issue, and instead argues that their injuries were "foreseeable." But lack of remoteness is

a separate requirement from foreseeability under West Virginia law, and Plaintiffs make no showing of clear error in the court's finding that Distributors' conduct was too remote to be a proximate cause of the alleged injuries. This failure provides an independent basis to affirm the judgment below.

3. ***Plaintiffs Failed To Prove Unreasonable Conduct***. A public nuisance claim requires proof of "an unreasonable interference with a right common to the general public." *Duff v. Morgantown Energy Assocs.*, 421 S.E. 2d 253, 257 & n.6 (W.Va. 1992). Applying this standard, the court made a finding of fact that "the distribution of medicine to support the legitimate medical needs of patients as determined by doctors exercising their medical judgment in good faith cannot be deemed an unreasonable interference with a right common to the general public." JA6498.

Plaintiffs' argument that Distributors' conduct was "unreasonable" because Distributors allegedly failed to comply with their regulatory obligations is directly contrary to the court's fact-findings. The court found that Distributors "[s]ubstantially [c]omplied with [t]heir [d]uties" to "[d]esign and [o]perate" a suspicious order monitoring system and to "[r]eport [s]uspicious [o]rder[s]," JA6369, and that "Plaintiffs [h]ave not [p]roved [d]iversion-control [f]ailures by [Distributors]," JA6403. This failure of proof provides another independent basis for affirmance. Contrary to Plaintiffs' argument, Br. 57, these record-based fact-

findings were not dependent on the court's construction of the CSA, and furthermore the court's interpretation of the CSA was correct.

4. ***West Virginia Public Nuisance Law Does Not Apply to Lawful Products.*** The court made the three findings of fact summarized above—no causation, no proximate cause, and no unreasonable conduct—based on the assumption that West Virginia public nuisance law applies to the distribution of lawful products. But the court also correctly held, as an independent basis for the judgment, that West Virginia public nuisance law does not extend to alleged harms arising out of the distribution of prescription opioids or other lawful products.

The court based this conclusion on its survey of more than a century of decisions of the Supreme Court of Appeals of West Virginia, which have consistently applied public nuisance law to interferences with public property or resources and have ***never*** applied public nuisance law to the distribution or sale of lawful products. The Restatement of Torts and influential decisions of other state courts support the court's holding. The holding is also consistent with this Court's directives that a court sitting in diversity should "respond conservatively" and "avoid interpreting" the law "in a manner that 'has not been approved'" by the state's highest court, *Knibbs v. Momphard*, 30 F.4th 200, 213 (4th Cir. 2022) (quoting *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 96 (4th Cir. 2011), and

should not "create or expand [a] State's public policy," *Moore v. Equitrans, L.P.*, 27 F.4th 211, 220 (4th Cir. 2022) (citation omitted).

5. ***Plaintiffs' Requested Relief Was Not a Proper Abatement Remedy***. Plaintiffs waived damages and sought only equitable relief in the form of "abatement." The court correctly held that Plaintiffs' requested relief (even had they proven their claim) was not a proper "abatement" remedy because "what [P]laintiffs seek is not relief from wrongful conduct" but rather "recovery for the extensive harms of opioid abuse and addiction." JA6515.

Plaintiffs were not seeking to "'abate' (enjoin or stop) the nuisance," but were seeking "recovery for the extensive harms of opioid abuse and addiction," JA6515, JA6518; *see State ex rel. AmerisourceBergen Drug Corp. v. Moats*, 859 S.E.2d 374, 394 (W.Va. 2021) ("'Abatement' is an equitable form of relief and is simply the act of eliminating or nullifying whatever is causing the public nuisance.") (Hutchinson, J., concurring in part) (quotation omitted)). Also, as a matter of federal equitable jurisdiction, Plaintiffs were not entitled to abatement relief because they did not, and could not, show they lacked an adequate legal remedy.

ARGUMENT

I. THE COURT CORRECTLY FOUND THAT PLAINTIFFS FAILED TO PROVE CAUSATION.

It is a "fundamental legal principle" that Plaintiffs cannot prevail on their public nuisance claim without establishing causation. *Sergent v. City of Charleston*,

549 S.E.2d 311, 320 (W.Va. 2001); *see also State v. Chase Sec., Inc.*, 424 S.E.2d 591, 599 (W.Va. 1992). Further, the "determination of causation is a question of fact." JA6499 (citing Fourth Circuit and West Virginia law).

Based on 50 pages of fact-findings, the court found that Plaintiffs "failed to meet their burden of proving causation." JA6511. This was based on the court's fact-findings that (1) Distributors did not cause the alleged "oversupply" of prescription opioids in Cabell/Huntington and (2) Distributors did not cause the diversion of prescription opioids.

Plaintiffs' brief largely ignores these two findings, instead addressing only the court's separate holding regarding ***proximate*** causation. *See* Br. 70-77; *infra* Part II. But the court's threshold no-causation findings are alone dispositive of Plaintiffs' public nuisance claim. *See Sergent*, 549 S.E.2d at 320.

A. The Court Correctly Found That Distributors Did Not Cause an "Oversupply" of Prescription Opioids.

1. *The Evidence Established That Doctors, Not Distributors, Determined the Volume of Prescription Opioids in Cabell/Huntington.*

The crux of Plaintiffs' theory at trial was that the "purportedly unreasonable volume of distributions"—*i.e.*, the alleged "oversupply" of prescription opioids—"caused an opioid epidemic." JA6500.

Citing the trial evidence more than 200 times, the court squarely rejected Plaintiffs' contention that Distributors caused an "unreasonable volume" of

prescription opioids in Cabell/Huntington. The evidence was undisputed that "the volume of prescription opioids was determined by ***doctors***, not distributors," JA6470, and that Distributors "shipped prescription opioids only to licensed pharmacies in response to demand created by prescriptions," JA6499-6500. The evidence demonstrated that Distributors shipped precisely the volume of opioids prescribed by doctors in Cabell/Huntington, and no more. JA2517:19-24.

Plaintiffs' expert witnesses uniformly conceded this fundamental point. Plaintiffs' expert Dr. Gupta testified that "the total volume of prescriptions determines the total volume of pills." JA6468. Another Plaintiffs' expert, Dr. McCann, described opioid prescribing and opioid distribution as "two sides of the same coin." JA6470. A third Plaintiffs' expert, Ms. Keller, testified that "shipments by distributors to pharmacies" are a "reflection of the prescribing because orders ultimately fill prescriptions that are written." JA6468.

The court further found that "[t]he overwhelming majority of doctors were acting in good faith when they made the decision to prescribe opioids." JA6472. Plaintiffs' witnesses again uniformly conceded this central point. Dr. Keyes, an epidemiologist, testified that the "overwhelming majority of doctors prescribe opioids to their patients in good faith." JA6473. The former head of DEA's Office of Diversion Control, Mr. Rannazzisi, testified that "99 percent of the doctors are perfect" and that "the overwhelming majority of prescribing in America is conducted

responsibly." JA6473-6474. Plaintiffs' addiction expert, Dr. Waller, testified that doctors "were acting in good faith" in prescribing opioids for chronic pain. JA6473. As the court noted, in 2006, DEA stated that "nearly every prescription issued by a physician in the United States is for a legitimate medical purpose." JA6474.

Based on this voluminous and uncontradicted record evidence, the court found that the "volume of prescription opioids in Cabell/Huntington was determined by the good faith prescribing decisions of doctors in accordance with established medical standards." JA6498.

Ignoring this overwhelming evidence, Plaintiffs baldly assert—with no citations to the record—that "[n]either medical evidence . . . nor the changing standard of care . . . justified the volume" of prescription opioids Distributors shipped into Cabell/Huntington. Br. 56-57. But the evidence and the court's fact-findings were directly to the contrary: (1) "the undertreatment of pain . . . has been recognized as a public health crisis for decades," JA6435 (quoting treatise circulated by the Board of Medicine to "every doctor in West Virginia" JA6455), (2) "[b]eginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids . . . for the long-term treatment of chronic non-cancer pain," JA6438; (3) these "changes in the standard of care led to an increase in the medical use of prescription opioids" by doctors acting in good faith to treat pain, JA6458; (4) "more doctors were prescribing opioids," "at higher

doses and for longer durations," JA6471; and (5) this "sea change" in prescribing led to a "fourfold" increase in "the supply of prescription opioids . . . between 1999 and 2010," JA6438.

Extensive record evidence also demonstrated that the standard of care for treating pain changed in West Virginia. This included evidence that (1) the West Virginia Board of Medicine issued numerous policy statements and publications to West Virginia doctors between 1997 and 2008 encouraging the use of prescription opioids for treating chronic pain, JA6441-6442, JA6454-6457; (2) the Federation of State Medical Boards (of which West Virginia is a member) issued model guidelines characterizing prescription opioids as "essential" for the treatment of chronic pain, JA6442-6445, JA6453-6454; (3) the Joint Commission on Accreditation of Health Care Organizations originated the concept of "Pain as the Fifth Vital Sign," which evinced "a more aggressive stance" in treating pain and was adhered to by West Virginia hospitals, JA6445-6451; (4) DEA and 21 healthcare organizations, including the American Medical Association, issued a joint statement identifying the undertreatment of pain as a serious problem and endorsing prescription opioids as "often the only treatment option that provides significant relief," JA6452; and (5) the State of West Virginia "passed laws that influenced doctors to prescribe more opioids to patients for chronic pain," JA6457.

These "changes in the standard of care led to a particular increase in opioid prescribing in West Virginia, which compared to the nation as a whole has an older population, more workers in industries that lead to pain and injuries, and more people who suffer from conditions that cause or contribute to chronic pain." JA6461. These facts were corroborated by Plaintiffs' medical and epidemiological experts, who testified that the West Virginia population has a higher prevalence of health conditions (such as arthritis and cancer) that could lead to increased needs for pain treatment, *see, e.g.*, JA2052:6-14, JA2053:8-2054:11, JA2054:24-2055:2, JA2057:21-25, JA2058:1-14, JA2058:21-2059:2; JA2464:24-2465:5, JA2466:8-17, JA2469:4-6.[7]

These findings defeat Plaintiffs' central claim that Distributors caused an "excessive volume" of prescription opioids in Cabell/Huntington. The court found—based largely on concessions by Plaintiffs' own witnesses—that any "oversupply" was caused by ***doctors*** prescribing in good faith pursuant to the then-prevailing standard of care, not Distributors. Further, "there was no evidence presented for the trier of fact to find that [Distributors] had anything to do with

[7] Given these demographic fact-findings, Plaintiffs' repeated assertion (*e.g.*, Br. 49, 52-53) that shipments into West Virginia or Cabell/Huntington exceeded national averages misses the point. Plaintiffs' expert epidemiologist testified she "would expect to see higher levels of opioid prescribing in West Virginia than in many other states." JA6462.

changing the standard of care." JA6463. The court found that "[n]o culpable acts by [Distributors] caused an oversupply of opioids in Cabell/Huntington." JA6499.[8]

The court therefore found that Plaintiffs "failed to meet their burden of proving causation," JA6511, on their core contention that Distributors caused the "unreasonable volume" of prescription opioids that "caused an opioid epidemic," JA6499-6500.[9]

2. *Plaintiffs Did Not Prove the "Appropriate" Volume of Prescription Opioids.*

While Plaintiffs assert that Distributors "shipped extreme volumes" of prescription opioids, Br. 72, Plaintiffs failed to prove what the appropriate volume should have been. That, too, is fatal to their case on causation.

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[8] In contrast, the court found that Plaintiffs "judicially admit[ted] that a deceptive advertising campaign by the manufacturers of prescription opioids played a role in changing the standard of care" and "that manufacturers made false or misleading marketing claims about prescription opioids." JA6464. "Plaintiffs presented no evidence that [D]istributors made any of these claims." JA6465.

[9] Plaintiffs (Br. 73) cite a pretrial MDL ruling that "causation *could be* established" by proof that "opioid distributors were responsible" for "massive increases in the supply of prescription opioids." *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4178617, at *4 (N.D. Ohio Sept. 3, 2019). But here the court found, on a full trial record, that Distributors were *not* "responsible" for the volume of prescription opioids in Cabell/Huntington. Similarly, Plaintiffs' citation (Br. 73) to an Ohio jury verdict finding a "causal inference" in a public nuisance claim is irrelevant because it involved a completely different factual record involving two Ohio counties' claims against *pharmacies*, whose role in the supply chain and regulatory obligations are different. *See* JA6509-6510.

As the court noted, "[a]lthough Plaintiffs allege that the volume of prescription opioids distributed in Cabell/Huntington was 'excessive,' they offered no evidence, expert or otherwise, of how many prescription opioids should have been distributed in Cabell/Huntington." JA6482. Plaintiffs' experts consistently disclaimed any knowledge or evaluation of the volume of prescription opioids needed for treating pain in Cabell/Huntington.[10]

This failure of proof is decisive on the facts of this case: (1) the West Virginia population has significant medical needs for pain treatment, JA6461-6462; (2) the "medical community" determined that it was "not doing enough to treat pain," JA6435; (3) the West Virginia medical community and legislature accordingly encouraged significantly increased prescribing of opioids, JA6441, JA6454-6457; (4) the record documented that "nearly every prescription issued by a physician in the United States is for a legitimate medical purpose," JA6474; and (5) every pill

[10] *See, e.g.*, JA2457:20-2458:10 (Plaintiffs' expert epidemiologist "ha[d] not undertaken a statistical evaluation" of how many prescription opioids were needed in Cabell/Huntington and "ha[d] not undertaken any analysis of the pain needs specifically in Cabell/Huntington"); JA2096:3-9 (Plaintiffs' data expert could not "tell this Court how many prescription opioids should have been distributed to Cabell County or the City of Huntington"); JA2295:4-7 (Plaintiffs' DEA expert had "not done any kind of analysis of the medical needs for prescription opioids in Cabell County or Huntington"); JA2510:11-17 (Plaintiffs' data expert could not "tell the Court what volume of opioids was the right volume that should have been prescribed in Cabell-Huntington at any point in time").

Distributors shipped was authorized by a quota that DEA set "based on estimated medical need and other delineated needs," JA2302:7-22.

Given these facts, Plaintiffs' failure to establish the volume of prescription opioids needed to meet the undisputed medical needs of the community, determined by the then-prevailing medical standard of care, left them with no evidence that Distributors shipped in excess of those medical needs. This was a fundamental failure of proof—it is not possible to claim something is "too much" without knowing what would be "enough." *See People v. Purdue Pharma L.P.*, No. 30-2014-00725287-CU-BT-CXC, 2021 WL 7186146, at *7 (Cal. Super. Dec. 14, 2021) ("[M]ere proof of a rise in opioid prescriptions does not, without more, prove there was also a rise in medically inappropriate opioid prescriptions.").

3. *Plaintiffs Did Not Prove that Rogue Doctors Drove the Volume of Prescription Opioids.*

Citing testimony from Plaintiffs' expert epidemiologist, the court found that "rogue pain clinics (sometimes called pill mills)" "do not explain in any significant way the expansion of opioid prescribing and opioid-related harm." JA6479-6480. Even more telling, the court found "***no evidence*** that ties any of [Distributors'] shipments to a pill mill in Cabell/Huntington." JA6479. The court further concluded that "even if there was some level of 'illegal prescribing' in Cabell/Huntington," the

evidence failed to show it "was significant enough to impact the overall volume of prescription opioids distributed by [Distributors]." JA6484.

Plaintiffs assert that "the top 1% of opioid prescribers in Cabell/Huntington" accounted for a large share of total dosage units. Br. 69. But there was no evidence that the "top 1%" of prescribers were prescribing improperly or acting inconsistent with then-prevailing medical standards of care. To the contrary, the evidence established that the overwhelming majority of doctors in Cabell/Huntington were operating in good faith and pursuant to prevailing standards of care. *See supra* p. 21. This included doctors in the top 1%—one of whom, for example, practiced at Cabell Huntington Hospital and was identified by the City of Huntington as playing a key role in its "Road to Recovery Plan" for addressing the opioid epidemic, *see* JA2513:18-JA2514:22.

B. The Court Correctly Found That Distributors Did Not Cause the Diversion at Issue.

While Plaintiffs' "theory of harm is based on the diversion of prescription opioids," JA6507, the court found "there is no admissible evidence in this case that [Distributors] ***caused diversion*** that resulted in an opioid epidemic," JA6511. That factual finding is uncontroverted.

There was no evidence that any prescription opioids were diverted "while in [Distributors'] custody or under their control." JA6507. Nor was there any evidence that any of Distributors' "pharmacy customers were engaging in diversion."

JA6508. "Plaintiffs offered no evidence that [Distributors] ever distributed controlled substances to any entity that it knew was dispensing for any purpose other than to fill legitimate prescriptions." JA6481. As the court correctly found, the "lack of evidence of pharmacy-level diversion on the part of [Distributors'] pharmacy customers is fatal to [P]laintiffs' claims." JA6508.[11]

The court also found as a matter of fact that Distributors did not cause any diversion ***after*** pharmacies dispensed prescription opioids. The "diversion that occurred downstream from [Distributors'] pharmacy customers," JA6510-6511, arose from "unused prescription opioids" being "diverted for [m]on[e]tary value" or "bartered for no cost among family and individuals in a shared social network," JA6460, and "involved criminal actions of third parties over whom [Distributors] had no control," JA6431.

The evidence showed that Distributors did not cause, and had no means of preventing, this type of diversion. Plaintiffs' DEA expert, Mr. Rafalski, testified that such diversion is not the responsibility of the distributor because "distributors have no control over what happens" after prescriptions are dispensed to patients. JA2308:7-11, JA2310:19-23. Similarly, the former head of DEA's Office of Diversion Control, Mr. Rannazzisi, testified that it is not the role of distributors to

[11] The only evidence of pharmacy-level diversion in Cabell/Huntington related to a pharmacy "which no [Distributor] serviced." JA6508.

"evaluate a patient's legitimate medical need for opioids" and that distributors are not required to "Know [Their] Customer's Customer"—*i.e.*, the patients to whom pharmacies dispense prescription medicines. JA2413:14-20, JA2414:3-7. Based on this and other evidence, the court found that Distributors could not prevent or control diversion that occurred ***after*** Distributors' pharmacy customers dispensed prescription opioids to patients. JA6431.

Heedless of the evidence and the court's fact-findings, Plaintiffs simply assert that Distributors' "diversion-control failures support the reasonable inference that [Distributors] caused the nuisance in Cabell/Huntington." Br. 72-73. The court specifically determined otherwise, finding there is "***no admissible evidence*** in this case that ***[Distributors] caused diversion*** that resulted in an opioid epidemic." JA6511. And Plaintiffs' use of the term "diversion-control failures" (without record support) is contradicted by the court's finding that Plaintiffs "[h]ave not [p]roved [d]iversion-control [f]ailures," JA6403; *see also infra* Part III.C.

Because Plaintiffs "cannot recover against [Distributors] by proving only that they were injured as a result of the opioid epidemic," JA6507, or "that someday, somehow, some of the opioids that [Distributors] shipped fell into the wrong hands," JA6511, their failure to prove that Distributors caused the diversion that allegedly harmed Plaintiffs is fatal to their public nuisance claim. They make no showing of

clear error (or any error) in the court's fact-finding that Plaintiffs "failed to meet their burden of proving causation," JA6511.

II. THE COURT CORRECTLY FOUND THAT PLAINTIFFS DID NOT PROVE PROXIMATE CAUSATION.

Beyond these no-causation findings, the court found separately that Plaintiffs "failed to meet their burden to prove that [Distributors'] conduct was the ***proximate*** cause of their injuries," JA6515, because, as a matter of fact, the alleged "oversupply" of prescription opioids was "made possible, beyond the supply of opioids by [Distributors], by overprescribing by doctors, dispensing by pharmacists of the excessive prescriptions, and diversion of the drugs to illegal usage—all effective intervening causes beyond the control of [Distributors]," JA6515. Given this "complex chain of causation," JA6514, the court found that "the [h]arms [t]hat Plaintiffs [c]laim [Distributors] [c]aused [a]re [t]oo [r]emote" to establish proximate causation, JA6511.

This remoteness holding was separate and apart from the court's threshold findings of no causation. Both of the court's ultimate fact-findings on causation (no causation and no proximate causation) are independently dispositive of this appeal.

A. The Court Applied the Correct Standard.

Under West Virginia law, "[a] remote cause of injury is insufficient to support a finding of proximate cause." JA6512 (citing *Metro v. Smith*, 124 S.E.2d 460, 464 (W.Va. 1962)); *see also Webb v. Sessler*, 63 S.E.2d 65, 69 (W.Va. 1951) ("remote

causes of the injury" are not "actionable"). A proximate cause is "that cause which in actual sequence unbroken by any independent cause, produced the wrong complained of, without which the wrong would not have occurred." *Coffield v. McArdle*, No. 21-0569, 2022 WL 3905239, at *6 (W.Va. Aug. 30, 2022) (quoting *Webb*, 63 S.E.2d at 68). The court applied that standard in reaching its conclusions on proximate cause, *see* JA6511-6512 (citing *Webb*). Plaintiffs agree this is the correct standard. *See* Br. 71.

Plaintiffs' brief never addresses the remoteness element of proximate causation. *See* Br. 70-77. Nor do they show clear error in the court's fact-finding that Distributors' conduct was remote from Plaintiffs' alleged injuries, which necessarily occurred ***after*** Distributors delivered prescription opioids to pharmacies, ***after*** pharmacies dispensed those medicines to patients pursuant to doctors' prescriptions, ***after*** patients or third parties transferred or used the pills illegally, and ***after*** still others used those pills illicitly. *See* JA6430-6431.

Instead, Plaintiffs fault the court for not addressing "foreseeability" or "concurrent causation" in evaluating proximate causation. Br. 73–77. But Plaintiffs ignore that remoteness—the basis of the court's finding on proximate causation—is distinct from foreseeability under West Virginia law. *See, e.g.*, *Humphrey v. Westchester Ltd. P'ship*, No. 17-0885, 2019 WL 2185972, at *7 (W.Va. May 21, 2019) (affirming grant of summary judgment on proximate causation grounds where

alleged injuries "were [too] remote in time and [too] remote from any alleged acts or omissions on the part of [defendant]"); *Metro*, 124 S.E.2d at 464; *Webb* 63 S.E.2d at 69.

Two closely analogous federal court decisions, applying West Virginia law, demonstrate why the court reached the correct conclusion on proximate causation. In *City of Charleston, West Virginia v. Joint Commission*, 473 F. Supp. 3d 596 (S.D.W.Va. 2020), plaintiff municipalities—including the City of Huntington—sued the body that accredits hospitals nationwide, alleging that its requirement that hospitals treat pain as "The Fifth Vital Sign" and its issuance of permissive "Pain Management Standards" led to "inappropriate provision of opioids," which in turn caused the municipalities to incur increased health care costs and other injuries. *Id.* at 606-07, 615-16. The court dismissed the municipalities' claims on proximate causation grounds, holding that "defendants' actions are too attenuated and influenced by too many intervening causes" and that "no injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means." *Id.* at 630-31. Reflecting the distinction between foreseeability and remoteness, the court found no proximate causation because the injury was remote from the defendant's conduct, even as it discussed foreseeability in determining whether the defendant owed plaintiffs a duty of care. *Id.* at 619-22.

Likewise, in *Employer Teamsters-Local Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 466 (S.D.W.Va. 2013), plaintiffs alleged that manufacturers' marketing of a prescription medicine led to higher reimbursement costs for health insurers. The court held that plaintiffs could not establish proximate causation because "[b]etween Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events, including the independent medical judgment of doctors." *Id.* at 475 (internal quotation omitted). The decision did not turn on whether increased prescribing was "foreseeable" or whether the manufacturer was a "concurrent cause," because it held that the manufacturer's conduct was too remote to constitute a proximate cause. *Id.*

The court correctly analogized this case to *City of Charleston* and *Employer Teamsters*.[12] *See* JA6513-6515. Here, as in those cases, multiple independent actions stand between Distributors' conduct in shipping medicines to licensed pharmacies and Plaintiffs' alleged injuries—notably, the professional judgments of

[12] Although both *City of Charleston* and *Employer Teamsters* included a discussion of the "directness" test set forth in *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992), both decisions applied West Virginia law and were based on principles of remoteness that are well-established in West Virginia law. *See City of Charleston*, 473 F. Supp. 3d at 628 (applying "the principles of remoteness to state law tort claims"); *Employer Teamsters*, 969 F. Supp. 2d at 473-75 (applying remoteness standard to West Virginia state law claims).

doctors (in prescribing medicines) and pharmacists (in dispensing medicines) and the illegal conduct of at least two actors (the third parties who share, steal, or sell the medicines, and still others who abuse them). *See* JA6515. As the court found, and as in *City of Charleston* and *Employers Teamsters*, those multiple independent and separate acts establish that Distributors' conduct is "[t]oo [r]emote" from Plaintiffs' claimed injuries to establish proximate causation. JA6511.[13]

Tellingly, Plaintiffs do not even mention *City of Charleston* or *Employer Teamsters*, let alone offer any response to the court's analysis of those cases or its findings on remoteness. Instead, as noted, Plaintiffs focus on "foreseeability" and "concurrent causation" (Br. 70-77)—two completely different considerations in the proximate causation analysis. Plaintiffs' argument therefore misses the point. Even if proximate cause requires a showing of foreseeability—as Plaintiffs contend—it also requires a showing that the defendant's conduct is not remote from the alleged harm. *See Metro*, 124 S.E.2d at 464 (conduct "must be a proximate, ***not a remote***, cause of injury").

[13] In *City of Charleston*, the court observed that the defendant healthcare accreditation organization was even further removed in the causal chain than wholesale distributors. *See* 473 F. Supp. 3d at 630–31. The court did not say proximate causation could be established as to distributors, but rather that the defendant's conduct was even more remote than distributors.

The distinction between "foreseeability" and "concurrent causation," on the one hand, and remoteness, on the other, is not controversial. The cases Plaintiffs cite illustrate that difference. In *Wehner v. Weinstein*, for example, the court noted that concurrent causation may arise "[w]here separate and distinct negligent acts of two or more persons continue unbroken to the instant of an injury, contributing ***directly and immediately*** thereto." 444 S.E.2d 27, 33 (W.Va. 1994). Plaintiffs also quote *Evans v. Farmer*, 133 S.E.2d 710, 717 (W.Va. 1963), for the proposition that two or more persons may be liable if they "together proximately cause" injuries. Br. 74. But these cases only confirm that concurrent causation involves circumstances where two or more persons are "direct" or "proximate" (*i.e.*, not remote) causes of an injury.

Plaintiffs' citation to "intervening act" cases, Br. 71-72, misses the point for the same reason. Here, the court did not conclude that the various independent actions discussed in its factual findings were "intervening acts" that defeat proximate causation as a matter of law. *See* JA6512-6515. Instead, it found that those actions—involving numerous independent actions of multiple actors—made Distributors' conduct "[t]oo [r]emote" from Plaintiffs' injuries as a matter of fact to constitute a proximate cause. JA6511.

B. The Court's Uncontested Fact-Findings Contradict Plaintiffs' Proximate Causation Arguments.

Aside from Plaintiffs' failure to show any legal error in the court's analysis of the remoteness requirement, their arguments are contrary to the court's findings of fact.

Plaintiffs argue that "concurrent causation" was established by Distributors' "profound diversion-control failures" and the "oversupply [Distributors] caused." Br. 70, 72, 74. But those assertions are refuted by the court's fact-findings that (1) "Plaintiffs [h]ave [n]ot [p]roved [d]iversion-control [f]ailures by [Distributors]," JA6403; (2) "[n]o culpable acts by [Distributors] caused an oversupply," JA6499; and (3) "doctors, ***not*** distributors" "determined" "the volume of prescription opioids," JA6470; *see also infra* Part III.C. Plaintiffs make no showing that those findings were clearly erroneous.

Likewise, Plaintiffs argue that "foreseeability" is satisfied because "[d]iversion was a foreseeable consequence of [Distributors'] misconduct." Br. 76. But the court determined as a matter of fact that ***there was no "misconduct"*** by Distributors, *see* JA6403—another finding that Plaintiffs do not show was clearly erroneous.

Plaintiffs' reliance on motion-to-dismiss rulings in other opioid cases fails for obvious reasons. Br. 77. Those pretrial rulings simply recognize that a plaintiff ***may*** be able to prove causation at trial, depending on the evidence presented. The court

made the same pretrial ruling in this case, giving Plaintiffs a full opportunity to prove proximate causation at trial. After hearing the evidence, the court found they failed to do so. JA6515.

III. THE COURT CORRECTLY FOUND THAT PLAINTIFFS FAILED TO PROVE DISTRIBUTORS UNREASONABLY INTERFERED WITH A PUBLIC RIGHT.

As Plaintiffs concede, a public nuisance under West Virginia law requires proof of "an unreasonable interference with a right common to the general public." Br. 31 (quoting *Duff v. Morgantown Energy Assocs.*, 421 S.E. 2d 253, 257 & n.6 (W.Va. 1992), which in turn quotes the Restatement (Second) Torts, § 821B). Whether a defendant's conduct is unreasonable is a question of fact. *Sticklen v. Kittle*, 287 S.E.2d 148, 161 (W.Va. 1981).

The court found as a matter of fact that there was "nothing unreasonable" about Distributors' shipment of opioid medications needed to fill the prescriptions written by doctors for treating their patients. JA6432; *see also* JA6497-6498. For that reason, the court concluded that "Plaintiffs failed to show that the volume of prescription opioids distributed in Cabell/Huntington was because of unreasonable conduct on the part of [Distributors]." JA6431.

Plaintiffs make no showing that these fact-findings were clearly erroneous. Similarly, Plaintiffs' argument that Distributors' conduct "was unreasonable because . . . they failed to comply with their duties under the CSA" (Br. 45) is

unsupported by the record and directly contrary to the court's findings of fact that Distributors substantially complied with their CSA obligations.

Plaintiffs are also wrong when they assert that these fact-findings on reasonableness are undermined by the court's supposedly "mistaken" interpretation of the CSA. The court correctly construed the CSA—for the reasons addressed *infra* in Part III.D. Further, the court's fact-findings of reasonableness, fully supported by the record evidence, do not depend on the court's construction of the CSA.

A. The Court Applied the Correct Standard.

The court held that, in determining whether conduct is an "unreasonable interference with a right common to the general public," it "must assess the gravity and avoidability of the harm, as well as the utility of defendants' conduct." JA6496-6497 (citing *Duff*, 421 S.E.2d at 257 n.6; *In re Flood Litig. Coal River Watershed*, 668 S.E.2d 203, 214 n.8 (W.Va. 2008)). Plaintiffs argue that this legal standard applies to private and ***not*** public nuisances. Br. 67-68. That is incorrect.

The Restatement (Second) of Torts explains that the public nuisance standard of unreasonableness is "substantially similar to that employed for the tort action for private nuisance"—namely, it is based on "weighing of the gravity of the harm against the utility of the conduct." Restatement (Second) of Torts, § 821B, cmt. *e* (1979). As the Restatement (Second) makes clear, in a public nuisance case, "in determining whether the gravity of the interference with the public right outweighs

the utility of the actor's conduct, it is necessary to consider the social value that the law attaches to the primary purpose of the conduct, the suitability of the conduct to the character of the locality and the impracticability of preventing or avoiding the invasion." *Id*. § 828, cmt. *a*.

The Supreme Court of Appeals of West Virginia, citing the Restatement, has adopted this balancing test for public nuisance cases. *See Duff*, 421 S.E.2d at 257 & n.6. *Duff* involved both private and public nuisances, and the court did not draw any distinction between the standard of unreasonableness applicable to each. *See id*.; *see also Hendricks v. Stalnaker*, 380 S.E.2d 198, 201 (W.Va. 1989) (the "reasonableness" inquiry for public and private nuisance is "simila[r]"). In fact, Plaintiffs themselves cite *Duff* as establishing "West Virginia's test of a public nuisance." Br. 27. Here, the court therefore was correct in applying that balancing test in determining whether Distributors' conduct was "unreasonable."

Plaintiffs' contention that the court failed to consider Distributors' conduct "in relation to the particular locality" (Br. 68) is incorrect. The court expressly examined the "volume of prescription opioids in Cabell/Huntington," JA6498, considered the "social costs incurred by communities such as [Cabell/Huntington]," JA6497, and evaluated evidence specific to these communities, *see*, *e.g.*, JA6468 (assessing prescribing by "[d]octors in Cabell/Huntington"); JA6479 (assessing lack of "shipments to a pill mill in Cabell/Huntington").

B. The Court Correctly Found That Distributors Acted Reasonably in Shipping Medicines Used To Fill Legitimate Prescriptions.

Plaintiffs argue that Distributors unreasonably interfered with a public right because they "shipped massive quantities of opioids to Cabell/Huntington." Br. 45. Again, that argument ignores the court's findings of fact. The court found "that the volume of prescription opioids was determined by doctors, not distributors," JA6470, who were acting in "good faith . . . in accordance with established medical standards," JA6498.

On the basis of these findings, which are fully supported in the record (and not challenged by Plaintiffs on appeal), the court found that "the distribution of medicine to support the legitimate medical needs of patients as determined by doctors exercising their medical judgment in good faith cannot be deemed an unreasonable interference with a right common to the general public." JA6498. Put differently, "there is nothing unreasonable about distributing controlled substances to fulfill legally written prescriptions." JA6431-6432; *see also Pope v. Edward M. Rude Carrier Corp.*, 75 S.E.2d 584, 589 (W.Va. 1953) (where conduct is "imperatively demand[ed]" for the "public convenience," it cannot be unreasonable or a public nuisance) (quotation omitted).[14]

[14] Plaintiffs suggest (Br. 68) that by citing *Pope* the court held that lawful, beneficial activities can never be nuisances. The court made no such holding, nor does *Pope* stand for that absolutist position. *Pope* weighed the dangers of the conduct at issue

C. The Court Correctly Found That Plaintiffs Failed To Prove CSA Violations.

Plaintiffs argue that Distributors unreasonably interfered with a public right because "they failed to comply with their duties under the CSA." Br. 45. That argument ignores the court's findings of fact on precisely this issue.

"A determination of substantial compliance is a fact-intensive inquiry and whether a defendant has substantially complied with the CSA is a question of fact." JA6364 (quoting *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2021 WL 3917174, at *3 (N.D. Ohio Sept. 1, 2021)). Based on more than 60 pages of detailed fact-findings, JA6369-6431—including direct evidence of DEA's repeated approval of Distributors' compliance programs—the court entitled an entire section of its decision with the finding that "Plaintiffs Have not Proved Diversion-control Failures by [Distributors]." JA6403. It likewise headed another section of its decision with the finding that Distributors "Substantially Complied with Their Duties under the CSA to Design and Operate a SOM System and Report Suspicious Orders." JA6369.

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against its social utility to evaluate whether it was unreasonable. *See* 75 S.E.2d at 589-90 (dynamite shipped on public roads was a "necessary article of commerce" and "a substance which the public convenience imperatively demands," "even though danger to persons or property . . . be necessarily incident to such transportation") (quotation omitted).

These findings are fatal to Plaintiffs' repeated assertions, without an evidentiary basis, that Distributors unreasonably interfered with a public right by violating their regulatory obligations.

1. *The Court Correctly Found That Plaintiffs' Liability Expert Was Not Credible or Persuasive.*

Mr. Rafalski was Plaintiffs' only witness who purported to testify about Distributors' alleged CSA violations in Cabell/Huntington.[15] The court thoroughly rejected Mr. Rafalski's testimony, excluding entirely his opinions on causation "for lack of a reliable methodology," JA6404-6405, and concluding that the remainder of his testimony was "unpersuasive," "factually unsupported," and "in sharp conflict" with other record evidence, JA6403-6418. On appeal, Plaintiffs largely abandon Mr. Rafalski, arguing only in passing that the court rejected his testimony because it purportedly misread the CSA. Br. 61, 65. But the court's reading of the CSA was correct, *see infra* Part III.D, and furthermore the court's fact-based reasons

[15] Plaintiffs also introduced fact testimony from Mr. Rannazzisi, but he admitted he could offer no testimony relevant to Cabell/Huntington. *See* JA2402:6-17 (could not identify any orders in Cabell/Huntington "that . . . should have been blocked by one of the defendants but were not"; "No, I have not reviewed any documents related to West Virginia.").

for rejecting Mr. Rafalski's testimony as unsupported and non-credible did not depend on its construction of the CSA.

Mr. Rafalski used an algorithm to flag shipped orders he claimed "were likely to be diverted." JA2314:6-12. No other witness purported to identify ***any*** orders Distributors shipped to Cabell/Huntington that were either suspicious or likely to be diverted, and Mr. Rafalski admitted that he had no basis for his algorithm: (1) he invented it entirely for litigation; (2) it has never been used by him, DEA, or any distributor outside of litigation; (3) he did not "actually review any of the orders" it flagged; (4) he could not say how many of the flagged orders qualified as "suspicious" under the CSA; and (5) the algorithm was completely disconnected from any evaluation of legitimate prescribing or changing standards of care.[16] It is no surprise, then, that the court found this and Mr. Rafalski's other testimony to be "unreliable," "unsupported," "unconvincing," and "entirely unpersuasive." JA6403-6405, JA6410-6411, JA6415, JA6429.

As the court found, "Plaintiffs did not prove that [Distributors] failed to maintain effective controls against diversion and design and operate sufficient SOM

[16] *See* JA2277:12-2288:21,JA2319:11-13, JA2319:5-10, JA2319:21-JA2320:11, JA2320:12-17, JA2320:18-21, JA2317:14-19, JA2330:6-20, JA2302:7-JA2303:1, JA2303:14-JA2304:1, JA2327:12-15, JA2330:1-5, JA2323:21-JA2324:6.

systems to do so." JA6403. Plaintiffs do not challenge these findings, let alone show they are clearly erroneous.

2. *Plaintiffs Failed To Prove That Distributors Wrongfully Shipped Suspicious Orders.*

Plaintiffs repeatedly assert that Distributors failed "to identify and investigate suspicious orders." *E.g.*, Br. 2, 27, 55, 56, 72, 77. The evidence and the court's findings of fact were directly to the contrary. "[A]t all relevant times, [Distributors] had in place suspicious order monitoring . . . systems as required by the CSA and its implementing regulations." JA6369.

In 45 pages of fact-findings, the court detailed each Distributor's suspicious order monitoring program, including enhancements made to those programs over time and changes in DEA's guidance to Distributors over time. JA6369-6403, JA6418-6428. The court specifically relied on contemporaneous documentary evidence showing that DEA endorsed the suspicious order monitoring methods Distributors employed. *See* JA6375 (referencing DEA letter "grant[ing] approval for earlier ABDC system"; "ABDC understood" from DEA that its later system was "the industry standard"); JA6387 (Cardinal "regularly communicated with the DEA" regarding its program and "DEA did not ask Cardinal . . . to change the system or fault it in any way"); JA6391, JA6401 (McKesson's program was "accepted by the DEA" and "DEA did not express any disagreement" with McKesson's program). These fact-findings were extensively supported by the court's credibility

assessments of Distributors' witnesses. *See*, *e.g.*, JA6418, JA6426 (finding Distributors' witnesses "persuasive," "credible" and "reliable in all respects").

Plaintiffs also argue that Distributors wrongfully "shipped [suspicious] orders," Br. 16, or failed to "block suspicious orders," Br. 46, 77. But that argument, too, is directly at odds with the court's findings. The court found that "[b]y 2008, each [Distributor] had in place a SOM program that blocked ***all*** suspicious orders they identified." JA6500.

Before then, the court found that DEA "understood and accepted that wholesale distribut[ors] would ship any suspicious orders that they identified and reported to the DEA." JA6500. The court found that it was only in 2007 that DEA issued informal guidance that Distributors should not ship suspicious orders. JA6372-6373; *see also* JA6500. This was supported by testimony that Mr. Rafalski gave in another case, while employed by DEA, acknowledging that the "do not ship" requirement was first announced in 2007.[17] JA2333:14-2346:19; JA2405:19-25,

[17] DEA's 2007 informal guidance that distributors should not ship suspicious orders—never codified to this day in a statute or regulation—"d[id] not have the force and effect of law" and could not create legally enforceable duties, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995); *N. Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 763 (4th Cir. 2012). The court "assume[d] without deciding" that the CSA "statutory and regulatory duties . . . includ[e] a duty not to ship suspicious orders" "[b]ecause it does not affect the outcome of this case under the evidence presented at trial." JA6416n.2.

JA2407:2-13. Those findings refute Plaintiffs' argument that Distributors' pre-2008 shipment of some "suspicious orders" was wrongful.

Further, while Distributors (based on DEA guidance) did not block all suspicious orders before 2008, they ***did*** block orders they believed were likely to be diverted. *See* JA6382 (Cardinal testimony that it cut off customers that "posed an unreasonable risk of diversion"); JA6393 (McKesson blocked all orders "that it believed were likely to be diverted"); JA2110:3-17 (if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them").

3. *Plaintiffs Failed To Prove That Distributors Did Not Conduct Adequate Due Diligence.*

At trial, Plaintiffs sought to prove that Distributors failed to engage in adequate due diligence of customers and their orders. But the court found Plaintiffs failed to prove these asserted deficiencies. JA6416-6428. Based on "extensive, persuasive evidence," the court found "that [Distributors] conducted due diligence." JA6416. And the court made detailed findings expressly rejecting Plaintiffs' criticisms regarding the setting of thresholds and threshold increases, *see* JA6371, JA6386-6388, JA6394-6396, JA6421, JA6423, JA6426—criticisms they raised repeatedly at trial and now ask this Court to re-try on appeal (Br. 50-55).

As the court found, DEA considered ABDC's system—which included provisions for thresholds and threshold increases—to be "the industry standard" that DEA "wanted other distributors to implement." JA6375. Likewise, the court found

that Cardinal Health shared with DEA its "procedures for setting customer thresholds" and that DEA did not take issue with those procedures and further found that "analysts on [Cardinal Health's] anti-diversion team" reviewed all "[o]rders that hit thresholds." JA6388. Similarly, the court found that "regulatory affairs personnel at McKesson" conducted "due diligence on ***each*** [threshold change request] prior to approval or rejection," and detailed the information that McKesson would review prior to making those decisions. JA6395-6396.

In making these findings, the court found the "evidence of [Distributors'] due diligence efforts persuasive" and found their witnesses who described these due diligence programs to be "credible." *See* JA6418 (crediting testimony of ABDC witnesses on its due diligence program); JA6426 ("Mr. Oriente testified regarding McKesson's due diligence, and the court found his testimony reliable in all respects."); JA6384-6388, JA6423-6425, JA6481 (crediting testimony of Cardinal Health's Vice President of Anti-Diversion Michael Moné).

The court rejected as "unsupported" Mr. Rafalski's "assumption that due diligence was not done," which he "stake[d] . . . on a lack of existing records in the discovery materials," and which the court found was "in sharp conflict with evidence that each [Distributor] engaged in extensive due diligence," JA6416-6418. The court relied on the fact that federal law "does not require that pharmacy diligence files or suspicious order reports be maintained for any minimum period of time,"

JA6417-6418; on "Mr. Rafalski's conce[ssion] on cross-examination that the fact [that] such diligence files are not still available is not necessarily indicative of whether the diligence was previously done and recorded," JA6417; and on the common-sense observation that "[t]he fact that [Distributors] do not currently maintain copies of certain due diligence files (many years later) is not a very persuasive indicator that due diligence was not completed or that the files did not previously exist," JA6418. The court therefore rejected Plaintiffs' invitation to draw an "inference that a lack of records means adequate due diligence was not done." JA6418. *See Vulcan Materials Co. v. Massiah*, 645 F.3d 249, 260 (4th Cir. 2011) (refusal to apply adverse inference must stand unless it was an abuse of discretion).[18]

In sum, after weighing the witnesses' credibility and extensively examining the evidence, the court found that Distributors undertook appropriate due diligence, both "during customer onboarding and for existing customers." JA6396 (McKesson); *accord* JA6384-6385 (Cardinal Health undertook "thorough evaluation[s] of new customers . . . and continuing diligence regarding existing

[18] Plaintiffs (Br. 65) misstate the facts and holding in *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 218-20 (D.C. Cir. 2017). There, the court found that "[r]ecords were absent, despite Masters' representation to DEA" that due diligence records were "*permanently retained*," thereby giving rise to the inference that no diligence was done. *Id*. at 218. In contrast, here, the evidence established that records were not permanently retained and that DEA imposed no such requirement on Distributors.

customers"); JA6377 (discussing ABDC's "enhanced . . . due diligence" both "for onboarding new pharmacies" and "existing customers").[19]

Based on these findings, the court found that Plaintiffs "***did not prove that [Distributors'] due diligence with respect to suspicious orders was inadequate***." JA6403. Plaintiffs simply ignore these extensive and well-supported fact-findings in asserting that Distributors did not perform adequate due diligence. Br. 47-48, 61.

4. *Drs. Webb and Fisher Do Not Establish CSA Violations.*

Plaintiffs contend that Distributors committed "misconduct" by not refusing to supply pharmacies that filled prescriptions from Drs. Webb and Fisher. Br. 55-57. This contention is entirely unsupported in the record. No witness offered testimony that Distributors acted improperly in relation to Drs. Webb and Fisher.

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[19] Plaintiffs make the demonstrably false claim that "McKesson conducted no diligence on Rite Aid orders at all: it let Rite Aid police itself." Br. 54; *see also* Br. 64. In fact, while a McKesson witness testified that McKesson worked cooperatively with Rite Aid's company-wide regulatory department, he also testified that McKesson performed its own diligence relating to Rite Aid. *See* JA2248:12-23, JA2248:24-107:5, JA2258:19-25, JA2259:1-3, JA2260:24-JA2261:7, JA2264:17-20. DEA was aware McKesson was operating in this manner and raised no objection. JA2248:7-JA2249:9. Plaintiffs also falsely contend that ABDC conducted no due diligence for three pharmacy customers. Br. 49-51. But internal documents and testimony from ABDC witnesses demonstrated that ABDC conducted due diligence on all of its Cabell/Huntington pharmacies, including the three mentioned by Plaintiffs. For example, Michael Perry, ABDC's sales representative in Cabell/Huntington, specifically testified that he routinely visited each of these pharmacies and did not observe any red flags. *See*, *e.g.*, JA2163:9-JA2165:18, JA2168:17-JA2169:13, JA2171:10-12, JA2171:16-21. Plaintiffs offer no credible rebuttal to any of this testimony on appeal.

Plaintiffs presented no evidence of the volume of allegedly illegitimate prescriptions by these doctors, the volume of these doctors' prescriptions dispensed by pharmacies served by Distributors, or that Distributors knew that prescriptions written by these doctors were illegitimate.

The court's fact-findings establish Plaintiffs' failure of proof as to Drs. Webb and Fisher: (1) "[t]here is no evidence that ties any of [Distributors'] shipments to a pill mill in Cabell/Huntington," JA6479; (2) "Plaintiffs offered no evidence that [Distributors] ever distributed controlled substances to any entity" they "knew was dispensing . . . other than to fill legitimate prescriptions," JA6481; and (3) "even if there was some level of 'illegal prescribing' in Cabell/Huntington," the evidence failed to show it "was significant enough to impact the overall volume of prescription opioids distributed," JA6484.

Apart from this failure of proof, the court's fact-findings also refute Plaintiffs' suggestion that Distributors should have refused to service pharmacies filling these doctors' prescriptions. Based on the evidence, and regulations establishing that the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," 21 C.F.R. § 1306.04(a), the court found that "Distributors have no control over the medical judgment of doctors" and "are not tasked with deciding whether the patient ought to get pain medication," JA6509. Nor do they have the "ability to stop pills on a prescription-by-prescription basis" or

any "expertise with which to determine whether prescriptions are good or bad." JA6510.[20]

5. *The DEA Settlements Do Not Establish CSA Violations.*

Plaintiffs accuse the court of "ignor[ing]" DEA settlement agreements with Distributors. *E.g.*, Br. 17-18, 66-67. Contrary to Plaintiffs' assertions, none of those settlement agreements contains any admission that any Distributor ***shipped*** any suspicious orders—much less that they did so to customers in Cabell/Huntington.[21]

More fundamentally, it is black-letter law that unproven allegations in settlement agreements are not admissible for purposes of establishing liability. *See*

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[20] These findings are amply supported by Plaintiffs' witnesses. Mr. Rannazzisi testified that distributors (1) cannot second-guess legitimate medical decisions by prescribers, JA2413:21-24; (2) cannot obtain the information needed to evaluate the medical needs of patients, JA2413:25-JA2414:2; and (3) cannot make the determination that a controlled substance is medically necessary for particular patients, JA2410:16-19. Similarly, Mr. Rafalski admitted that doctors and not distributors are responsible for deciding whether opioids are an appropriate treatment, and that distributors do not have access to data on individual prescriptions needed to make any such assessment. JA2291:15-JA2292:22, JA2298:25-JA2299:13.

[21] McKesson's 2017 settlement agreement contained a limited "acceptance of responsibility" but was admitted only for "notice"—and not "for the truth" of the matters asserted. *See* JA2220:12-20 (admitting 2008 settlement on limited basis); JA2223:1-7 (admitting 2017 settlement "on same basis"). In any event, that limited "acceptance of responsibility" related only to reporting of suspicious orders, and said nothing about shipping or "failing to block" suspicious orders. JA2421:14-16; *see also* JA2254:23-JA2255:14. As for Cardinal Health's 2012 settlement agreement, its limited admissions concerned only its Lakeland, Florida distribution center and four Florida customers. JA2175:7-24. That distribution center did not service Cardinal Health's customers in West Virginia. JA2191:15-20.

Macsherry v. Sparrows Point, LLC, 973 F.3d 212, 224 (4th Cir. 2020); *Wyatt v. Sec. Inn Food & Beverage, Inc.*, 819 F.2d 69, 71 (4th Cir. 1987). The settlement agreements therefore cannot be considered "to prove or disprove" Plaintiffs' claims. Fed. R. Evid. 408(a).

* * *

Plaintiffs did not prove their claim (Br. 45) that Distributors engaged in "unreasonable conduct" by supposedly violating their CSA obligations. The court found that, while Distributors' "systems had imperfections," JA6500, each "[s]ubstantially [c]omplied" with its obligation under the CSA to maintain effective controls against diversion, JA6369, and Plaintiffs "[h]ave [n]ot [p]roved [d]iversion-control failures" by Distributors, JA6403.

Plaintiffs make no showing that the court's fact-findings of substantial compliance are clearly erroneous. Those findings defeat Plaintiffs' assertions that Distributors' regulatory compliance establishes "unreasonable conduct."

D. The Court Correctly Construed the CSA.

Unable to point to admissible, credible record evidence of CSA violations, Plaintiffs argue that the court "[m]isinterpreted and [m]isapplied the CSA." Br. 57. But Plaintiffs' arguments do not establish legal error; nor do they provide a basis to disturb the court's record-based fact-findings of Distributors' regulatory compliance, which are independent of its CSA analysis.

Plaintiffs first assert that the court held Distributors "have no obligation to scrutinize or block their customers' orders." Br. 28, 57, 62. That grossly mischaracterizes the court's decision. The court devoted 45 pages of fact-findings to Distributors' programs for evaluating customers' ***orders***, JA6369-6403, and found that "at all relevant times, [Distributors] had in place ***suspicious order*** monitoring . . . systems as required by the CSA and its implementing regulations," JA6369. Plaintiffs further ignore the undisputed record evidence that Distributors have blocked ***all*** suspicious orders since at least 2008. JA6500.

Plaintiffs next claim that the court erred in rejecting their position that Distributors' regulatory obligations extend to preventing "downstream transactions"—such as patients "selling or giving away their medications" or "acquaintances stealing" them—that occur long after they are dispensed to the patient. *E.g.*, Br. 7, 9, 57. The court properly rejected this liability theory, explaining that "a concept of diversion that creates distributor liability for downstream conduct is unsupportable," JA6511, and that "maintaining effective controls" against diversion does not require distributors to undertake the impossible task of "prevent[ing] controlled substances from eventually falling into the wrong hands at some point in their existence," JA6508-6509. That conclusion was correct as both a factual and legal matter.

First, the court made a factual finding, based on extensive record evidence, that "[a]ny diversion of prescription opioids" in Cabell/Huntington "after the medicines were distributed to and dispensed by bona fide pharmacies" involved "criminal actions of third parties over whom [Distributors] had no control, including the persons to whom the medicines were prescribed and those involved in diverting the prescription opioids." JA6430-6431. As discussed above, Plaintiffs' own witnesses agreed with that point, *see supra* pp. 29-31, and there was no evidence to support a contrary finding.

Second, the court made a legal determination, separate and apart from that factual finding, that distributors have no obligation to prevent diversion that occurs after pharmacies dispense prescription opioids to patients pursuant to legitimate prescriptions. JA6502-6511. That conclusion is directly supported by the CSA's implementing regulations, which provide that a wholesale distributor's obligation to "maintain effective controls against diversion" involves only maintaining the physical security of controlled substances while in the distributor's physical custody and developing a system to identify and report suspicious orders to DEA.[22] *See*

[22] As the court found, Distributors complied with this obligation because "at all relevant times" they "had in place suspicious order monitoring . . . systems." JA6369.

supra pp. 13-15. The regulation says nothing about preventing diversion that occurs after opioids have been dispensed by pharmacies.

Plaintiffs ignore the plain language and clear limits of the regulation and assert that the court "misread key precedent." Br. 59-60. But, in fact, the court correctly concluded that all "the major cases" Plaintiffs have "tried to analogize to this one" "involved distributors supplying dispensers [*i.e.*, pharmacies] that were essentially in the diversion business, not the legitimate dispensing business." JA6503.

As the court noted, "the diversion at issue" in these cases "was not some concept of pills eventually falling into the wrong hands—it was the distributor ***placing them in the wrong hands***." JA6506-6507 (emphasis in original). In *Masters Pharmaceuticals, Inc.*, for example, DEA found the distributor had "significant information that raised a strong suspicion that each of the ***pharmacies*** was engaged in illegitimate dispensing practices." 80 Fed. Reg. 55,418, at 55,486. On appeal, the court found that the distributor "could not confirm that the ***pharmacy's*** dispensing practices were consistent with those of a legitimate business." *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 218-20 (D.C. Cir. 2017). In *Southwood Pharmaceuticals, Inc.*, DEA found that the distributor had "obvious indications" that its ***pharmacy customers*** "were not filling lawful prescriptions." 72 Fed. Reg. 36,487, at 36,500. And in *Direct Sales Co. v. United States*, the court evaluated the

doctor's illegitimate prescribing because the doctor was the distributor's direct customer. 319 U.S. 703, 705 (1943).

There was no such evidence here of Distributors placing prescription opioids "in the wrong hands." The court found that "Plaintiffs offered ***no evidence***" (1) "of any diversion from [Distributors'] pharmacy customers in Cabell/Huntington," JA6429, or (2) that Distributors "ever distributed controlled substances to any entity that it knew was dispensing for any purpose other than to fill legitimate prescriptions written by doctors," JA6481. Accordingly, the court found "no persuasive evidence" that Distributors shipped orders of prescription opioids to pharmacies that were dispensing those medicines inappropriately. JA6506-6507. Plaintiffs' argument that the court misconstrued the CSA or misapplied it to these facts has no basis.

IV. THE COURT CORRECTLY HELD THAT WEST VIRGINIA PUBLIC NUISANCE LAW DOES NOT EXTEND TO THE DISTRIBUTION OF LAWFUL PRODUCTS.

Based on its findings of no causation, no proximate causation, and no "unreasonable interference" with a public right, the court found as a matter of fact that Plaintiffs failed to prove their public nuisance claim on three separate factual bases. The court also correctly held as a matter of law that Plaintiffs could not assert a public nuisance claim under West Virginia law based on the distribution of FDA-approved medicines. The court noted that the Supreme Court of Appeals of West Virginia has never applied public nuisance law to the distribution of lawful products,

and it soundly reasoned that, "if confronted with the option to extend the law of public nuisance to the sale, distribution, and manufacture of opioids, the Supreme Court of Appeals of West Virginia would decline with good reason to do so." JA6496.

The court based this holding on its review of more than 100 years of West Virginia public nuisance law, and on authorities federal district courts should consider in "forecast[ing] a decision of the state's highest court": "restatements of the law, treatises, recent pronouncements of general rules or policies by the state's highest court, well considered dicta" and "the practices of other states." JA6489 (quoting *Wells v. Liddy*, 186 F.3d 505, 528 (4th Cir. 1999) and *St. Paul Fire Ins. v. Am. Intern. Spec. Lines*, 365 F.3d 263, 2727 (4th Cir. 2004)).[23]

The court also followed this Court's admonition that it "should 'respond ***conservatively*** when asked to discern governing principles of state law and take care

[23] Plaintiffs repeatedly cite (Br. 26, 32-33) the general principle that "the outcome of the litigation" in diversity jurisdiction "should be substantially the same, so far as legal rules determine the outcome of a litigation, as it would be if tried in a State court." *Ferens v. John Deere Co.*, 494 U.S. 516, 524 (1990) (quotation omitted). But that does not alter the *Erie* principle that when a court sits in diversity the "legal rules" are determined by decisions of the State's highest court, not the miscellaneous trial court orders on which Plaintiffs rely. *See Comm'r of Internal Rev. v. Bosch*, 387 U.S. 456, 465 (1967) (a "State's highest court is the best authority on its own law"); *Twin City Fire Ins. Co. v. Ben Arnold-Sunbelt Bev. Co.*, 433 F.3d 365, 370 (4th Cir. 2005) ("a federal court sitting in diversity is not bound by a state trial court's decision on matters of state law").

to avoid interpreting that law in a manner that has not been approved' by the West Virginia Supreme Court of Appeals." JA6489-6490 (quoting *Knibbs v. Momphard*, 30 F.4th 200, 213 (4th Cir. 2022) (quotation omitted)). As this Court recently reiterated, a court sitting in diversity "should not create or expand [a] State's public policy." *Moore v. Equitrans, L.P.*, 27 F.4th 211, 220 (4th Cir. 2022) (quotation omitted); *Rhodes v. E.I. duPont de Nemours & Co.*, 636 F.3d 88, 96-98 (4th Cir. 2011) (declining to extend West Virginia public nuisance law beyond the scope recognized by the Supreme Court of Appeals of West Virginia).

A. West Virginia Public Nuisance Law Covers Only Interferences With Public Property or Resources.

The Supreme Court of Appeals of West Virginia has long followed the Restatement of Torts' definition of public nuisance: "an unreasonable interference with a right common to the general public." *Duff*, 421 S.E.2d at 257 n.6. That is, West Virginia public nuisance law applies only when the conduct at issue interferes with "an interest shared equally by members of the public." *Rhodes*, 636 F.3d at 96.

Reflecting these limiting principles, the court noted that "the West Virginia Supreme Court has applied public nuisance law only in the context of conduct that interferes with public property or resources." JA6490. To support that conclusion, the court relied on a survey of West Virginia nuisance cases (both public and private) from 1878 to 1982 in *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 621 (W.Va. 1985). As the court noted, "[e]very case listed" in *Sharon Steel* "concerned

the misuse, or interference with, public property or resources." JA6490-6491. One common category of public nuisance cases involves harm to publicly-shared resources such as clean air and water.[24] The other principal category involves physical interferences with public property, including "obstructions to highways, public grounds, harbors, and landings."[25]

Plaintiffs' assertion that the Supreme Court of Appeals of West Virginia "has applied [public nuisance law] to the manufacture and distribution of products," Br. 32, 37, is wrong. "None of the cases cited" in *Sharon Steel* "held that distribution or sale of a product could constitute a public nuisance." JA6491. For instance, the defendant in *Kermit Lumber* sold lumber, but the court did not hold that selling lumber was a public nuisance. Rather, *Kermit Lumber* (and *Sharon Steel*) involved use of the defendant's property to pollute public resources (air, land, and water) with hazardous waste, as Plaintiffs acknowledge. *See* Br. 32 (*Sharon Steel* concerned

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[24] *See, e.g.*, *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 488 S.E.2d 901 (W.Va. 1997) (hazardous waste at defendant's business site); *Sharon Steel Corp.*, 334 S.E.2d 616 (hazardous waste facility at location of defendant's former coking plant); *Harris v. Poulton*, 127 S.E. 647 (W.Va. 1925) (garage on defendant's property used to store flammable materials and emitted late-night noises); *Parker v. City of Fairmont*, 79 S.E. 660 (W.Va. 1913) (dye works on defendant's property emitted soot and smoke).

[25] *State v. Ehrlick*, 64 S.E. 935, 938-39 (W.Va. 1909); *see also, e.g.*, *Higginbotham v. Kearse,* 161 S.E. 37 (W.Va. 1931) (door swung open into public sidewalk); *City of Elkins v. Donohoe*, 81 S.E. 1130 (W.Va. 1914) ("obstruction of a public street by an individual is a public nuisance"); *Davis v. Spragg*, 79 S.E. 652 (W.Va. 1913) (awning erected over public street).

"hazardous waste generated at a coking plant"; *Kermit Lumber* concerned "hazards generated in the process of treating lumber"). Likewise, even though *Wilson v. Phoenix Powder* involved a product (explosives), the application of public nuisance law was not to that product, but to the defendant's use of its mill "dangerously near to public places," including public roads, which posed a "constant danger impending over those highways and all lawfully using them." 21 S.E. 1035, 1036 (W.Va. 1895). Thus, it was a standard case of the defendant using its property to endanger persons enjoying public spaces nearby.[26]

Although public nuisance law is "adaptable to a wide variety of factual situations," *Sharon Steel*, 334 S.E.2d at 621, this flexibility has bounds. In West Virginia, it has been consistently confined to these traditional categories of harm and has ***not*** been extended to the distribution and sale of lawful products—and certainly

[26] Plaintiffs (Br. 37) cite *Mahoney v. Walter*, 205 S.E.2d 692 (W.Va. 1974) and *Martin v. Williams*, 93 S.E.2d 835 (W.Va. 1956) for the proposition that "lawful businesses . . . may become a nuisance"—a general principle that is not in dispute and does not aid Plaintiffs' argument. Both were private nuisance cases, involving the operation of a salvage yard and used car lot in residential neighborhoods, respectively. Both involved operation of these businesses in ways that interfered with the private enjoyment of personal residences and did not turn on whether lawful products were being sold or whether the products were harmful. *See Mahoney*, 205 S.E.2d at 699 (evaluating salvage yard's impact on "basically a residential area"); *Martin*, 93 S.E.2d at 839 (assessing used car lot's impact on "an exclusive residential district").

not to cases where the alleged harm is personal injury from consumers' use of a product.

Plaintiffs' assertion that "[t]here is no principled distinction between harms to public health that occur during production and that occur as a result of use" of a product (Br. 38)—made without citation to any authority—has no basis in West Virginia law. More than a century of West Virginia cases establishes that public nuisance law has been consistently applied to cases involving interferences with public resources or property—because those are the circumstances that can give rise to an interference with a "right common to the general public," *Duff*, 421 S.E.2d at 257 n.6, or "an interest shared equally by members of the public," *Rhodes*, 636 F.3d at 96. *See State v. Lead Indus. Ass'n*, 951 A.2d 428, 453 (R.I. 2008) ("[t]he term public right is reserved more appropriately for those indivisible resources shared by the public at large, such as air, water, or public rights of way").

Conversely, injuries suffered by use of or exposure to a product inherently do not involve interests "common to the general public" or "shared equally by members of the public." Rather, when products harm individuals (as when an individual illicitly uses diverted prescription opioids), there is, at most, a violation of the ***private right*** not to be personally injured, as the Restatement makes clear in distinguishing public from private rights. *See* Restatement (Second) of Torts §821B, cmt. *g* (1979) (a public right is "collective in nature and not like the individual right that everyone

has not to be assaulted or defamed or defrauded or negligently injured"); *see also Lead Indus.*, 951 A.2d at 448 ("a public right is more than an aggregate of private rights by a large number of injured people").

Plaintiffs' position, if accepted, would mean that every seller of a product that arguably affects public health—whether it be alcohol, fatty foods, lead paint, guns, cell phones, or others—could be liable for public nuisance. *See City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004) (rejecting argument "that there is a public right to be free from the threat that some individuals may use an otherwise legal product . . . in a manner that may create a risk of harm to another"); *Lead Indus.*, 951 A.2d at 954-55. That is not the law in West Virginia, or elsewhere.

As the court observed, "[t]o apply the law of public nuisance to the sale, marketing and distribution of products would invite litigation against any product with a known risk of harm, regardless of the benefits conferred on the public from proper use of the product." JA6495. Given this Court's instruction that a court exercising diversity jurisdiction should not "create or expand [a] State's public policy," *Moore,* 27 F.4th 220, and given these profound public policy ramifications, the court was correct in rejecting this dramatic re-writing of West Virginia public nuisance law.

B. The Restatements of Torts Support the Court's Conclusion.

In reaching its conclusions about the limits of West Virginia public nuisance law, the court properly relied on both the Restatement (Second) of Torts, as adopted by the Supreme Court of Appeals of West Virginia, and the more recent Restatement (Third) of Torts' clarification of that standard. *See* JA6490.

Comment *g* to Section 8 of the Restatement (Third) explains that liability for public nuisance based on products "has been rejected by most courts, and is excluded by [the Restatement], because the common law of public nuisance is an inapt vehicle for addressing the conduct at issue." *Id.* "Mass harms caused by dangerous products are better addressed through the law of products liability, which has been developed and refined with sensitivity to the various policies at stake." *Id.*

While Plaintiffs criticize the court (Br. 38-40) for relying on the Restatement (Third), that reliance was fully justified. This Court has instructed that Restatements are among the core materials courts should consider in making *Erie* predictions. *See Moore*, 27 F.4th at 220. Although the Supreme Court of Appeals of West Virginia has yet to refer to the Restatement (Third), it has consistently relied on the Restatement (Second)'s definition of public nuisance, *see, e.g., Duff*, 421 S.E.2d at 257 n.6, and the Restatement (Third) does not change that definition but rather

explains and clarifies it, *see id*. § 8, cmt. *a*.[27] The Restatement (Third) adopted this clarification due to "confusion about [the] scope" of the Restatement (Second), including a misimpression that public nuisance law covers "anything injurious to public health and safety." Restatement (Third) § 8, cmts. *b*, *g*. That misimpression is precisely what Plaintiffs are urging this Court to write into West Virginia law.[28]

C. The Court's Decision Is Supported By the Most Persuasive Rulings from Other States.

In undertaking its *Erie* prediction, the court also surveyed the rulings of other appellate courts and relied on the most persuasive. In particular, the court recognized that its holding was supported by the only state supreme court decision addressing the scope of public nuisance in the opioid context—the Oklahoma Supreme Court's decision in *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719 (Okla. 2021), issued after a full trial against an opioid manufacturer, holding that "public nuisance

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[27] Plaintiffs assert that courts in other states have rejected the Restatement (Third) (Br. 39-40 n.11), but those cases did not address the provisions on which the court relied here. Plaintiffs also assert that the Restatement (Second) "recognizes public nuisance cases involving the sale of products," citing the Reporter's Note to § 821B. Br. 39 & n.10. But those cases do not appear in the Reporter's Note. They were decided many years after Section 821B was published, and are merely listed in the case citations that follow Section 821B in updated versions, with no indication of approval.

[28] Although Plaintiffs and the Legal Scholars amici assert that Section 8 of the Restatement (Third) addresses only private parties' claims for public nuisance (Br. 39–40; Leg. Sch. Br. 15), comment *g* clearly encompasses governmental suits because the Reporter's Note relies on several oft-cited governmental cases, making clear that the comment is not limited to private suits.

law does not extend to the manufacturing, marketing, and selling of prescription opioids." *Id*. at 721.

As support, the Oklahoma court cited a long list of public nuisance cases dating back to 1909, establishing that Oklahoma law (like West Virginia's) addresses the pollution of public resources and interference with public thoroughfares, not lawful products. *Id*. at 724 n.13. While Plaintiffs suggest that the Oklahoma court only relied on a historical interpretation of Oklahoma's nuisance statute (Br. 43), in fact its decision also relied on both the Restatement (Second) and Restatement (Third). *See id*. at 724-26. Consistent with West Virginia law, the Oklahoma court recognized that "a public right is a right to . . . an indivisible resource . . . like air, water, or public rights-of-way," and that "[t]he manufacture and distribution of products rarely, if ever, causes a violation of a public right." *Id.* at 726 (internal quotation omitted).

The court also found persuasive the Oklahoma court's insight that extending public nuisance law to prescription opioids or other products "would allow courts to manage public policy matters that should be dealt with by the legislative and executive branches of government—not by courts." JA6493 (citing *Johnson & Johnson*, 499 P.3d at 731). Many states, including West Virginia, supported this principle in litigation related to climate change, arguing that public nuisance law should not apply because "[t]here are no judicially enforceable common law

'nuisance' standards to apply, or any practical limitation on the judicial policymaking role" with respect to large-scale social issues that are "more appropriately addressed by other branches of government."[29]

The trial court likewise relied on cases rejecting claims against makers and sellers of other products, such as asbestos, lead paint, and guns, in which courts enforced traditional limits on the scope of public nuisance. *See* JA6494-6496.[30] These cases supported the court's prediction that the Supreme Court of Appeals of West Virginia would not extend public nuisance law to cover the distribution of products, because "a public right so broad and undefined would subject any potentially dangerous instrumentality to suit," making nuisance "a monster that would devour in one gulp the entire law of tort." JA6495.

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[29] Amicus Br. of Indiana and Fourteen Others States In Support of Dismissal, *People of the State of Calif. v. BP P.L.C.*, Nos. C 17-06011 WHA, C 17-06012 WHA, 2018 WL 1916332 (N.D. Cal. April 19, 2018).

[30] *See, e.g.*, *Beretta U.S.A. Corp.*, 821 N.E.2d at 1116 (expressing "reluctan[ce] to recognize a public right so broad and undefined that the presence of any potentially dangerous instrumentality in the community could be deemed to threaten it"); *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007) (concluding that allowing nuisance suits for the sale and distribution of a product would "supplant an ordinary product liability claim with a separate cause of action as to which there are apparently no bounds"); *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 761 N.Y.S.2d 192, 196 (2003) (concluding that "giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance").

Plaintiffs argue that the court ignored the majority of opioid-related decisions that purportedly apply public nuisance law to prescription opioids. Br. 35 n.7, 42-43. That is misleading because the decisions Plaintiffs cite are unpublished denials of pretrial motions issued with little to no reasoning. The persuasive value of these decisions pales in comparison to the court's thorough and learned opinion, after a full trial, as well as the Oklahoma Supreme Court's opinion (also based on a full trial record) and those of other state supreme courts cited immediately above.

D. The Court Correctly Rejected Reliance on West Virginia Lower Court Decisions.

The court observed that, in applying *Erie* principles, it should "consider lower court decisions but is not bound to follow them if the federal court believes they would not be affirmed by the states' highest court." JA6489 (citing Chemerinsky, Federal Jurisdiction, 6th ed. 354-55); *see also Twin City Fire*, 433 F.3d at 370 ("a federal court sitting in diversity is not bound by a state trial court's decision on matters of state law").

The court concluded that two West Virginia lower court decisions, *Brooke County* and *Morrisey*,[31] that apply "the law of public nuisance to sale and distribution of opioids" were "not persuasive" and are "inconsistent with the Restatement of

[31] *Brooke County Comm'n v. Purdue Pharma*, No. 17-c-248, 2018 WL 11242293 (W.Va. Cir. Ct. Dec. 28, 2018); *State ex rel. Morrisey v. Amerisource-Bergen*, No. 12-c-141, 2014 WL 12814021 (W.Va. Cir. Ct. Dec. 12, 2014).

Torts that has been favorably commented upon by the West Virginia Supreme Court of Appeals." JA6492. "Both cases were decided on motions to dismiss the complaint which contained other causes of action besides public nuisance." *Id*. "[N]either case contained an in-depth consideration of the question" or "considered the adverse economic consequences of extending the law of nuisance to the sale or distribution of opioids or the expansion of nuisance law to cover other dangerous products." *Id*. Also, neither case identified any Supreme Court of Appeals of West Virginia decision applying public nuisance law to the distribution of a lawful product, nor could they.[32]

Plaintiffs suggest that these trial court decisions should have more weight because the Supreme Court of Appeals of West Virginia denied discretionary petitions for review or writs of prohibition. Br. 33-35. But those denials of discretionary review have no precedential value. *State ex rel. Miller v. Stone*, 607 S.E.2d 485, 488 n.3 (W.Va. 2004); *Perrine v. E.I. du Pont de Nemours & Co.*, 694 S.E.2d 815, 854 n.45 (W.Va. 2010).

[32] Plaintiffs also assert (Br. 41) that the court "ignored" *Lemongello v. Will Co., Inc,*, No. Civ.A. 02-C-2952, 2003 WL 21488208 (W.Va. Cir. Ct. June 19, 2003). But that unpublished trial court order denying a motion to dismiss has even less reasoning than *Brooke County*, simply stating in a single sentence without citation to any case law "that West Virginia law does not limit claims of public nuisance to those dealing with real property." *Id*. at *2. That was not the issue addressed by the court here.

Plaintiffs also refer to two orders of the West Virginia Mass Litigation Panel ("MLP"), another state trial court, denying motions to dismiss and summary judgment. Br. 34. But as Plaintiffs acknowledge, Br. 34, those MLP orders were based on the *Brooke County* and *Morrisey* decisions that the court found "not persuasive," "inconsistent with the Restatement of Torts," and devoid of meaningful reasoning. JA6492.[33]

V. THE COURT CORRECTLY HELD THAT PLAINTIFFS' REQUESTED RELIEF WAS NOT A PROPER ABATEMENT REMEDY.

Plaintiffs "waived all claims for damages" and sought "only the equitable remedy of abatement." JA6515; *see* Br. 78. On "a full trial record," the court concluded "that under the facts of this case, the relief that plaintiffs seek is not properly understood as abatement." JA6519. The court found that, despite Plaintiffs' disclaimer, they were in fact seeking damages—"remuneration for the costs of treating the horrendous harms of opioid use and abuse"—and were "not seeking to 'abate' (enjoin or stop) the nuisance." JA6518.

Plaintiffs' proposed "abatement" plan did ***not*** include any provisions addressed to Distributors' conduct generally or their distribution of prescription

[33] Plaintiffs additionally quote from a subsequent MLP order that declined to follow the court's decision here. Br. 34-35, 38. But that order similarly relies on *Brooke County* and *Morrisey* and therefore adds nothing to the court's conclusion that this line of lower court decisions was not persuasive.

opioids in Cabell/Huntington specifically. It did not (1) "recommend any new licensing requirements for distributors," (2) "propose any new reporting requirements for distributors," or (3) "propose any new physical security requirements for distributors." JA2581:19-22, JA2582:7-17, JA2582:19-22.

Instead, Plaintiffs sought a $2.5 billion fund primarily to treat addiction. JA6584. The court rightly found that money to pay for such medical treatment constituted traditional personal injury damages, not equitable abatement.[34] Plaintiffs also sought money to pay for other harms and programs related to drug abuse and addiction, including (1) medical treatment for diseases caused by intravenous drug use, (2) police and drug-related criminal justice programs, (3) needle exchanges for intravenous drug users and fentanyl testing for illegal opioids, (4) programs to reintegrate individuals released from incarceration, (5) training for health professionals on prescribing opioids, (6) counseling for "compassion fatigue" among first responders, and (7) enhanced programs to address homelessness and unemployment among drug abusers. JA2550:23-JA2551:5, JA2586:10-22, JA2591:12-25, JA2593:19-JA2601:8.

Plaintiffs conceded the breadth of the medical treatment, programs, and services encompassed within their requested $2.5 billion fund. *See* Br. 21-22

[34] The costs of medical treatment are, of course, a classic component of damages. *See* Dobbs, Law of Remedies (3d ed.) §8.1(3).

(requested relief included programs and services for "[p]revention," "[t]reatment," "[r]ecovery" and "[s]pecial [p]opulations"). Plaintiffs also conceded that the requested relief would provide medical treatment and other services for people (1) who had ***never used prescription opioids*** but were addicted to other drugs, (2) who became addicted to opioids distributed by wholesalers ***other than Distributors*** or who became addicted elsewhere and moved to Cabell/Huntington, and (3) who first used opioids and become addicted years into the future, well after judgment was entered in this case. *See, e.g.*, JA2578:16-22, JA2604:10-13, JA2604:19-JA2605:9. As the court correctly found (and Plaintiffs do not dispute), this requested relief "addresses harms caused by opioid abuse and addiction—it does not address [Distributors'] conduct." JA6485.

A. The Court Correctly Held That Abatement Concerns Stopping Nuisance-Creating Conduct or Conditions.

West Virginia case law establishes that a nuisance is conduct that interferes with a public right. *See Kermit Lumber*, 488 S.E.2d at 925 n.28 (public nuisance is "the ***doing of or the failure to do something***"); *Pope*, 75 S.E.2d at 589 ("[p]ublic nuisances always arise out of unlawful ***acts***"); *Duff*, 421 S.E.2d at 262 ("the proposed trucking may constitute a nuisance ***once it is operational***").

Quoting Supreme Court of Appeals of West Virginia decisions that an "act or condition" can be a nuisance, Plaintiffs argue that the nuisance is the resulting ***harm***—here, allegedly, the opioid epidemic in all its dimensions—not the alleged

actionable conduct. Br. 80-82. But the decisions Plaintiffs quote demonstrate that a nuisance is defined by the defendant's conduct and, in some cases, the physical conditions directly related to that conduct—not the personal injuries or other harms caused by that conduct. In *Martin*, for example, the Supreme Court of Appeals of West Virginia held that operation of a used car lot in a residential neighborhood was a private nuisance. 93 S.E.2d at 844. The court referred to the nuisance as an "act or condition," but the so-called "condition" concerned the conduct of the defendant in operating the car lot—using lights, displays, and equipment in ways that interfered with the homeowners' use and enjoyment of their own property. *Id*.

Similarly, in *Kermit Lumber*, the relevant conduct was the depositing of arsenic "on the Kermit Lumber business site in amounts above the regulatory limits," which then "flow[ed] into the Tug Fork River." 488 S.E.2d at 925. To the extent the resulting pollution was a "condition," that condition was the direct physical manifestation in the water and soil of the defendant's act of depositing excessive levels of arsenic. *See id.*

In both cases, the "condition" was indistinguishable from and coextensive with the actionable, objectionable conduct and did not extend to personal injuries or other harms associated with the nuisance-creating conduct (*e.g.*, illness or disease from drinking arsenic-polluted water, or depreciated property values due to an adjacent car lot).

Because a nuisance consists of conduct, the court properly held that the remedy of equitable abatement must seek to "'abate' (enjoin or stop)" the "alleged nuisance-causing conduct," JA6518-6519, and must have a "direct relation" to the "alleged misconduct," JA6518. *See Burch v. Nedpower Mount Storm, LLC*, 647 S.E.2d 879, 891 (W.Va. 2007) (where a plaintiff has successfully proven that conduct is a nuisance, a court may "abate the ***activity***"); *Moats*, 859 S.E.2d at 394 ("'Abatement' is an equitable form of relief and is simply the act of eliminating or nullifying whatever is causing the public nuisance.") (Hutchinson, J., concurring in part) (quotation omitted)).

In appropriate circumstances, abatement may also extend to eliminating the physical manifestation of the nuisance-creating conduct, such as removing a wrongfully-built structure, accumulated debris, or polluting contaminants. *See*, *e.g.*, *Martin*, 93 S.E.2d at 836 (removal of the "light poles, wires, lights, equipment, installations and structures used . . . in the conduct of the used car sales business"); *Kermit Lumber*, 488 S.E.2d at 925 n.29 (removal of arsenic-polluted soil); *Witteried v. City of Charles Town*, No. 17–0310, 2018 WL 2175820, at *3 (W.Va. May 11, 2018) (demolition of nuisance-creating structure) (cited at Br. 80, 83-84).

None of these cases held that abatement could extend to treating personal injuries caused by the nuisance, such as sickness caused by exposure to the nuisance-creating conduct. For example, the abatement remedy in *Kermit Lumber* did not

include compensation for medical treatment for personal injuries caused by arsenic exposure. *See* JA6519-6520. While Plaintiffs discount this by noting that personal injuries were not at issue in *Kermit Lumber*, Br. 84, that is precisely the point. When plaintiffs sue for personal injuries caused by the use of or exposure to harmful products, they bring negligence or product liability claims, not claims for abatement of a nuisance.

Likewise, in *West v. National Mines Corp.*, 285 S.E.2d 670, 679 (W.Va. 1981), the court held that excessive dust created by the defendant's trucking operations was a nuisance and entered an injunction requiring abatement of the nuisance (*i.e.*, by eliminating the dust). Although the plaintiffs alleged a number of harms caused by the excessive dust (such as impaired breathing, spoiled food and fouled water), the injunction to abate the nuisance did not extend to treating those injuries or other harms and was limited to stopping the nuisance-creating dust. *Id.* at 673.

B. The Court Correctly Found That Plaintiffs' Requested Relief Was Unrelated to Distributors' Alleged Conduct.

Under these principles, the court found, as a matter of fact, that Plaintiffs' requested relief was not a proper abatement remedy because "it does not address [Distributors'] conduct" and instead "is addressed" "[v]irtually [in its] . . . entirety," "to programs and services to treat opioid addiction and abuse, and the attendant harms caused by opioid abuse and addiction." JA6485. In stark contrast to the

abatement cases they cite, Plaintiffs did not seek to (1) stop Distributors from distributing prescription opioids or dismantle the distribution centers that service Cabell/Huntington (as in *Martin*); (2) change the way Distributors carry out their business (as in *West*); or (3) require Distributors to remove excessive pills from the community (as in *Kermit Lumber*).

Thus, the court concluded "that under the facts of this case, the relief that [P]laintiffs seek is not properly understood as abatement," JA6520, because "what [P]laintiffs seek is not relief from wrongful conduct" (*i.e.*, the alleged oversupply of opioids) but rather "recovery for the extensive harms of opioid abuse and addiction." JA6515.

Plaintiffs' primary response is to suggest that the court improperly "limit[ed] abatement to injunctions." Br. 82-84. But the court did no such thing. The court's observation that West Virginia decisions traditionally have limited abatement to injunctions reflected its recognition that an abatement remedy is to "'abate' (enjoin or stop) the nuisance." JA6518; *see also Duff*, 421 S.E.2d at 258 ("courts generally grant injunctions to abate existing nuisances").

Plaintiffs also suggest that the court held that abatement could never include the payment of money. *See* Br. 78-80, 83, 85. But again, the court said no such thing; it never suggested that monetary relief would not be a proper abatement remedy ***if*** tailored to address the "alleged nuisance-causing conduct," JA6518-6519.

In fact, the court held before trial that payment of money ***could*** properly be part of an abatement remedy if supported by the evidence. JA2008-2009 ("If the facts prove that an injunction requiring remediation would not be feasible, it is unclear why the court could not order funding as the functional equivalent."); *see also* JA1947-1957.

Finally, Plaintiffs are incorrect in suggesting (Br. 79) that the decision in *Moats* supports their abatement case. There, the Supreme Court of Appeals of West Virginia decided a writ petition in the "early stages of these cases," 859 S.E.2d at 385 n.54; "neither the parties nor the judges [had] explored the scope of potential remedies," and "all of the arguments raised by the defendants" on the proper scope of equitable relief were left "for future resolution." *Id.* at 394-95 (Hutchison, J., concurring).[35]

In contrast, here, "upon a full trial record" and "under the facts of this case," Plaintiffs failed as matter of fact to prove their entitlement to relief. JA6519-6520.

[35] For the same reason, the MDL and MLP pretrial rulings that Plaintiffs cite (Br. 86-87) did not resolve the appropriate scope of abatement relief but simply denied motions to dismiss.

C. Federal Common Law Bars Plaintiffs' Relief.

Plaintiffs failed to prove their entitlement to abatement relief for a separate reason, which Distributors argued below but the court did not need to reach given its ruling that Plaintiffs were not seeking a proper abatement remedy.

Federal common law governs the scope of equitable relief in federal court, including cases in which jurisdiction is based on diversity of citizenship. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (citing *Russell v. Southard*, 53 U.S. 139, 147 (1851)); *see also Sonner v. Premier Nutrition Corp.*, 49 F.4th 1300, 1302-03 (9th Cir. 2022). Whatever the state law requirements for equitable relief, a federal court cannot award equitable relief—whether an injunction, restitution, disgorgement, or abatement—unless there is no adequate remedy at law. *See Guar. Trust Co. of N.Y. v. York*, 326 U.S. 99, 105-06 (1945) ("Equitable relief in a federal court is of course subject to restrictions: . . . a plain, adequate and complete remedy at law must be wanting"); *Sonner*, 971 F.3d at 841 ("state law cannot expand or limit a federal court's equitable authority"); *SSMC, Inc. N.V. v. Steffen*, 102 F.3d 704, 708 (4th Cir. 1996).

Here, damages were an adequate and available remedy, as Plaintiffs alleged in suing Distributors for damages, JA1841-1842, JA1860, and as is plain from the fact that Plaintiffs sought solely monetary relief. But Plaintiffs waived their claim for damages. JA6515.

CONCLUSION

For the foregoing reasons, the trial court's decision should be affirmed.

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Respectfully submitted,

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 22-1819(L) **Caption:** City of Huntington v. AmerisourceBergen Drug. Corp.

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(s) Paul W. Schmidt

Party Name McKesson Corporation

Dated: April 17, 2023

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This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Rule 32(a)(6) because counsel prepared this brief in Microsoft Word 2016, using a proportionally spaced typeface: 14-point Times New Roman. This brief complies with the type-volume limitation of Rule 32(a)(7)(B)(ii), as modified by subsequent order of the Court dated December 14, 2022 (Dkt. No. 40), which granted leave to file a brief not in excess of 18,000 words, because this brief contains 17,937 words, excluding the parts of the brief exempted by Rule 32(f).

Dated: April 17, 2023

/s/ Paul W. Schmidt

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CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2023, I directed to be electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all parties or their counsel of record are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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